RISK BASED RECALL INTERVAL FOR CARIES MANAGEMENT AMONGST 11-12-YEAR-OLD PAKISTANI CHILDREN

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RISK BASED RECALL INTERVAL FOR CARIES MANAGEMENT AMONG 11-12-YEAR-OLD PAKISTANI CHILDREN

ABSTRACT

Introduction: In Pakistan, there are minimal resources allocated for primary dental care, and this has contributed to the high prevalence of dental caries. The mean DMFT score amongst 12-year-old Pakistani children is low, ranging from 1.2 to 2.5, which suggests a slow caries progression. This makes the traditional six-month recall interval inappropriate for caries management for this population. To indirectly overcome the problem of limited resources, the logical approach is to adopt risk-adjusted patient-centred strategies as dental visits made at regular intervals may increase treatment cost, are time-consuming, and may create supplier-induced demand. Recall interval periods on the bases of risk assessment has been recommended with extended period proposed for individuals with low caries risk, and shorter period for individuals identified as high risk for caries.

Objectives: This study aimed to recommend the appropriate recall interval period for caries management among 11-12-year Pakistani school children. The specific objectives were to determine the caries risk levels using reduced Cariogram and caries risk predictors in 11-12-year-old Pakistani school children, to assess the agreement on caries detection rate between the modified International Caries Detection and Assessment System and the WHO methods, to determine the predictability of reduced Cariogram, and to determine the rate of caries progression over an 18-month period using the WHO and ICDAS methods. Based on the data obtained, a recommendation on the appropriate dental recall interval for 11-12-year-old Pakistani school children will be made.

Material and Methods: A prospective longitudinal study of 18-month duration was conducted from May 2016 to October 2017 using convenient sampling in seven schools of the Bhakkar city of Punjab, Pakistan. A pilot study was conducted to evaluate the acceptability of the research instruments. In this study, a three-day prospective diet diary was used to record diet content. A reduced Cariogram program was used to assess the children's caries risk level. Intraoral assessments were performed using WHO and modified ICDAS methods. Caries progression rate was estimated using adjusted caries increment (ADJCI) at non-cavitated and cavitated thresholds. The predictability of reduced Cariogram was tested using the Receiver Operating Characteristic (ROC) analysis. The recommendations of caries recall interval was made by comparing the mean caries increment at baseline with the mean caries increment that occurred at all follow-ups, within risk categories, on cavitated and non-cavitated lesions.

Results: The reduced Cariogram program identified 40% of children as low, 30.5% as medium and 29.7% as high caries risk. Past caries experience and cariogenic food intake before bedtime were identified as significant predictors of caries risk. The predictability of the reduced Cariogram was 0.63 at 6 months, 0.65 at 12 month and 0.70 at 18 months. There was no significant difference in the values of DMFS/DMFT and prevalence of dental caries of the WHO method as compared to the modified ICDAS II at cut-off 2. At cut-off 3-6 (cavitated lesions), significant mean caries increment was observed in the high-risk category as compared to low and medium risk categories at all follow-ups. At cut-off A-6 (both cavitated and non-cavitated lesions), significant mean caries increment was observed in all risk categories at all follow-ups. Based on aforementioned findings, recall intervals for caries management in cavitated lesion is 12 months for low and medium-risk children, and six months for high-risk Pakistani 11-12-year-old children respectively. On the other hand, recall intervals for caries management in both non-cavitated and cavitated lesion is 6 months for low, medium-risk and high-risk Pakistani 11-12-year-old children respectively.

Conclusion: Depending on the level of caries risk and the clinical features of the carious lesions (cavitated or non-cavitated), the recommended caries recall interval for Pakistani children aged 11-12 years old varies from 6 to 12 months.

Keywords: Dental recall, Caries risk assessment, ICDAS, DMFT, Caries increment

RISKIO BERDASARKAN PENGURUSAN RISIKO UNTUK PENGURUSAN CARIT TERHADAP ANAK-ANAK PAKISTAN 11-12 TAHUN

ABSTRAK

Pengenalan: Di Pakistan, terdapat sumber yang minimum yang diperuntukkan untuk rawatan pergigian utama, dan ini telah menyumbang kepada prevalens karies gigi yang tinggi. Skor purata DMFT di kalangan kanak-kanak Pakistan berusia 12 tahun adalah rendah, antara 1.2 hingga 2.5, yang menunjukkan perkembangan karies perlahan. Ini menjadikan selang lawatan pergigian tradisional iaitu enam bulan tidak sesuai untuk pengurusan karies bagi penduduk ini. Untuk secara tidak langsung mengatasi masalah sumber yang terhad, pendekatan logik adalah mengamalkan strategi berteraskan risiko dan berpusatkan pesakit kerana lawatan pergigian yang dibuat pada selang masa yang tetap boleh meningkatkan kos rawatan, memakan masa, dan boleh mewujudkan permintaan yang disebabkan oleh pembekal. Tempoh selang lawatan pergigian pada asas penilaian risiko telah dicadangkan dengan tempoh lanjutan untuk individu yang mempunyai risiko karies yang rendah, dan tempoh yang lebih pendek untuk individu yang dikenal pasti sebagai risiko tinggi untuk karies.

Objektif: Kajian ini bertujuan untuk mengesyorkan tempoh selang lawatan pergigian yang sesuai untuk pengurusan karies di kalangan kanak-kanak sekolah berumur 11-12 tahun di Pakistan. Objektif khusus ialah menentukan tahap risiko karies dengan menggunakan Cariogram dan prediktor risiko karies untuk kanak-kanak sekolah Pakistan berusia 11-12 tahun, untuk menilai persefahaman mengenai kadar pengesanan karies di antara kaedah ICDAS yang diubahsuai dan kaedah WHO, untuk menilai kebolehramalan reduced Cariogram, dan menentukan kadar perkembangan karies sepanjang tempoh 18 bulan menggunakan kaedah WHO dan ICDAS. Berdasarkan data yang diperolehi, cadangan mengenai selang pengulangan lawatan pergigian yang bersesuaian untuk kanak-kanak sekolah Pakistan berusia 11-12 tahun akan dibuat.

Bahan dan Kaedah: Kajian jangka panjang selama 18 bulan dijalankan dari Mei 2016 hingga Oktober 2017 dengan menggunakan pensampelan mudah di tujuh sekolah di bandar Bhakkar, Punjab, Pakistan. Satu kajian perintis dijalankan untuk menilai kebolehterimaan instrumen penyelidikan. Dalam kajian ini, buku harian prospektif diet selama tiga hari digunakan untuk merakam kandungan diet. Program reduced Cariogram digunakan untuk menilai paras risiko karies kanak-kanak. Penilaian intraoral dilakukan menggunakan kaedah WHO dan kaedah ICDAS yang telah diubahsuai. Kadar progresi karies dianggarkan dengan menggunakan analisa kenaikan karies yang diselaraskan (ADJCI) di ambang lesi berlubang dan tidak berlubang. Kebolehramalan reduced Cariogram diuji menggunakan analisis Receiver Operating Characteristic (ROC). Cadangan selang lawatan pergigian dilakukan dengan membandingkan kenaikan karies purata pada asas dengan kenaikan karies purata yang berlaku pada semua susulan, dalam kategori risiko, pada lesi berkaviti dan tidak berkaviti.

Keputusan: Program reduced Cariogram mengenal pasti 40% kanak-kanak yang rendah, 30.5% yang sederhana dan 29.7% yang tinggi risiko karies. Pengalaman karies yang lalu dan pengambilan makanan kariogenik sebelum tidur telah dikenal pasti sebagai peramal penting risiko karies. Kebolehramalan bagi reduced Cariogram adalah 0.63 pada 6 bulan, 0.65 pada 12 bulan dan 0.70 pada 18 bulan. Tidak terdapat perbezaan yang signifikan dalam nilai DMFS / DMFT dan prevalens karies gigi apabila kaedah WHO dibandingkan dengan ICDAS yang diubahsuai pada keratan 2. Pada keratan 3-6 (lesi berkaviti), kenaikan karies yang signifikan diperhatikan dalam kategori berisiko tinggi berbanding kategori risiko rendah dan sederhana pada semua susulan. Pada keratan A-6 (kedua-dua lesi berkaviti dan tidak berkaviti), kenaikan karies yang signifikan diperhatikan dalam semua kategori risiko di semua susulan. Berdasarkan penemuan yang disebutkan di atas, selang pengulangan lawatan pergigian berasaskan risiko untuk pengurusan karies di lesi berkaviti kanak-kanak Pakistan berusia 11-12 tahun adalah 12 bulan untuk risiko rendah,

12 bulan untuk risiko sederhana dan 6 bulan untuk risiko tinggi masing-masing. Selang pengulangan lawatan pergigian berasaskan risiko untuk pengurusan karies kanak-kanak berusia 11-12 tahun di Pakistan dalam kedua-dua lesi tanpa kaviti dan berkaviti adalah 6 bulan untuk ketiga-tiga kategori risiko karies (rendah, sederhana dan tinggi).

Kesimpulan: Bergantung pada tahap risiko karies dan ciri-ciri klinikal lesi karies (berlubang atau tidak berlubang), selang pengulangan lawatan pergigian yang disyorkan untuk kanak-kanak Pakistan berumur 11-12 tahun bervariasi dari 6 hingga 12 bulan.

Kata kunci: Selang lawatan pergigian, Penilaian risiko karies, ICDAS, DMFT, Kenaikan karies

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LIST OF SYMBOLS AND ABBREVIATIONS

CRA	: Caries Risk Assessment
CAT	: Caries Risk Assessment Tool
CAMBRA	: Caries Management by Risk Assessment
ICDAS	: International Caries Detection and Assessment system
Modified ICDAS	: Modified International Caries Detection and Assessment system
DMFT	: Decayed Missing and Filled Teeth
DMFS	: Decayed Missing and Filled Surfaces
AAPD	: American Academy of Paediatric Dentistry
NICE	: National Institute for Health and Care Excellence
SE	: Sensitivity
SP	: Specificity
LED	: Light Emitting Diode
CCI	: Crude Caries Increment
NCI	: Net Caries Increment
ADJCI	: Adjusted Caries Increment
TSS	: Transition Scoring System
GDP	: Gross Domestic Product
RHC	: Rural Health Centres
BHU	: Basic Health Units
ECL	: Early Carious Lesion
MCAR	: Missing Completely at Random
MAR	: Missing At Random
D_TMFS	: Non cavitated plus cavitated lesion
D_CMFS	: Cavitated Lesion
ROC	: Receivers Operating Characteristic
DFS	: Dietary Free Sugar
WHO	: World Health Organization

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CHAPTER 1: INTRODUCTION

The current debate regarding the best recall interval between two dental examinations for the preventive dental care of children and adults is still underway (Kay, 1999; Renson, 2000; Sheiham, 2000; Lahti et al., 2001; Clarkson et al., 2009). This can be attributed to the inconsistency of the pieces of evidence obtained through the studies on the 'merits and demerits of regular and irregular dental visits'. For example, some literature reported that with regular dental visits, the quality of life of the patients would improve and there would be fewer chances of teeth being left untreated. This would consequently result in the reduction of tooth loss, more retained teeth and fewer chances of experiencing dental pain and emergency dental procedures (Sheiham et al., 1985; Murray 1996; McGrath, 2001). However, on the contrary, the available literature reports that there is no significant difference in the oral health of individuals receiving care at regular or irregular intervals (Sheiham et al., 1985; Reekie, 1997). Dental visits made at regular intervals are not necessarily useful in preventing the early onset of diseases. Instead, the increase in treatment cost, time consumption and chances of over-treatment have been linked with dental visits (Sheiham et al., 1985; Reekie, 1997).

The debate on recall interval has become more complicated by current variations in the epidemiology of oral disorders; especially, dental caries. The rates of prevalence and progression of dental caries have reduced significantly after the 1970s in the developed countries, as compared to the developing nations (Pitts, 1983; Brown & Selwitz, 1995; Mejare et al., 2004). Additionally, a difference in the experience of caries among patients of different ages and individuals with different incomes is evident in the literature (Hausen, 1997; Burt & Eklund, 1999). The rate of caries progression through enamel into dentine plays a vital role in determining the frequency of dental recalls (Sheiham & Sabah, 2010). The frequency of caries advancement from enamel to dentin in primary molar is faster as compared to the permanent teeth's (Koch, & Poulsen, 2009; Arrow, 2007; Fejerskov, & Kidd, 2008; Heymann et al., 2013).

The period of dental recall interval itself makes this debate more complicated because the duration of the recall interval period for every patient is different. The reason could be the uncertainty among dentist regarding the appropriate period of recall interval or the absence of a rational, information-based approach required for selecting the interval (Petitti, 1993; Riley et al., 2013). These variations have led to the designing of recall interval periods on the bases of risk assessment for every different individual with extended period for an individual with low risk and shorter period for individuals identified as high risk for caries (Perlus, 1994; Riordan, 1997; Deep, 2000; Taylor, 2000; Lahti et al., 2001; Clarkson et al., 2009; American Academy of Paediatric Dentistry, 2014).

Risk assessment facilitates practitioners in planning the appropriate management depending on personal caries risk level and to determine the proper recall interval. Caries risk assessment (CRA) is a crucial component of patient-centred caries management (Tellez et al., 2013). Several caries risk estimation tools have been developed such as caries risk assessment tool (CAT) and caries management by risk assessment (CAMBRA) (Young et al., 2007b; American Academy of Paediatric Dentistry, 2014). The earlier versions of caries risk assessment tools were paper-based, but later a computerised programme was introduced known as Cariogram. The Cariogram program has been shown to be able to demonstrate an overall risk situation and has been proved useful in evaluating caries risk (Fontana & Zero, 2006; Tellez et al., 2013). It was designed to determine the association between dental caries and its related risk factors. The results are produced in a graphic presentation constitutes of the level of caries risk and the chance a person has to avoid caries. A proposed prescription of a preventive therapy according to the risk levels can then be made. Factors for caries risk assessment included in the

Cariogram are previous caries experience, history of systemic diseases, the composition of diet and its frequency, the amount of plaque accumulation, count of mutans streptococci, access to fluoride sources, saliva secretion, buffering capacity, and professional clinical judgment (Brathall et al., 2004).

The Cariogram can be applied in two different ways, the full Cariogram application and reduced Cariogram (Gao et al., 2013; Petersson et al., 2010b). The use of full Cariogram requires bacterial and saliva testing to achieve an appropriate risk assessment. However, these assessments are not available to every dentist, and its application is time-consuming and expensive (Graham, 2009). Despite the exclusion of bacterial and saliva testing, recent studies have shown that reduced Cariogram can still be used to identify low-risk subjects. Previous evidence has shown that reduced Cariogram has higher specificity and sensitivity as compared to reasoning based risk assessment tools such as CAT and CAMBRA screening (Gao et al., 2013).

Current management of dental caries is provided by applying preventive and non-operative interventions (Pitts et al., 2011). Such an approach would require the identification of individual caries risk, carious lesion depth and activity of a lesion (Fontana & Zero, 2006; Pitts et al., 2011). In recent years, a new caries recording system namely the International Caries Detection and Assessment system (lCDAS) has been developed. This method records caries from a first visual change in enamel to an extended cavity in the dentine. It involves detailed visual examination and has improved reliability, sensitivity and specificity (Ismail et al., 2007). The ICDAS has two variants which are the full ICDAS and modified ICDAS. Both variants differ in terms of coding. The full ICDAS consist of 6 codes that range from 0-6. On the other hand, the modified ICDAS merged Code 1 and 2 as Code A, thus giving a total of 6 codes altogether. However, both variants can be applied to measure caries in epidemiological surveys (Braga et al., 2009a; De Amorim et al., 2012; lranzoCorte’s & AlmerichSilla, 2013). However, the only factor which can limit the use of ICDAS in surveys is the longer examination time (Braga et al., 2009a; lranzoCorte's & AlmerichSilla, 2013).

When primary health care was first established in Pakistan, oral health care was neglected. National public oral health policy does not exist, and most of the health budget allocations are towards the control of communicable disease with a high death rate (Harchandani, 2012). Pakistan lacks adequate oral health workforce in both rural and urban areas (Pakistan Medical and Dental Council, 2015; Government of Pakistan, 2003). In addition to that, family health programme activities launched by the government usually do not include oral health promotion. Private organisations and dental communities mostly offer oral health promotion programmes, but the numbers are limited (Khan et al., 2004). Consequently, this has resulted in significant gaps in the distribution of oral health care services. To make the situation worse, Pakistan is a low fluoride country, and it lacks the resources that are required to execute water fluoridation. Only 20% of the population has access to piped water supply, with the remaining using natural water resources (Khan et al., 2004). Hence, there is a need for alternative sources of fluoride in Pakistan. The limited availability of both resources and oral health promotion activities in Pakistan may be the reasons why its children's carious teeth are often left untreated or extracted due to pain (Government of Pakistan 2003; Khan et al., 2004).

To date, the oral health care services in Pakistan are mostly based on the treatment philosophy; however, this method fails to treat the rapidly spreading dental disorders such as dental caries (Government of Pakistan, 2003; Zhu, 2005; Beaglehole et al., 2009). A pathfinder survey conducted in 21 districts of Pakistan reported that the prevalence of dental caries in 12-year-old children is 50% with a mean DMFT score ranging from 1.2 – 2.5 (Government of Pakistan, 2003; Shah et al., 2011). Currently, in Pakistan, the WHO method (DMFT/DMFS) is used to measure dental caries. However, this method has significant limitations where it only measures cavities with dentinal involvement, it does not record caries progression, and it is unable to predict teeth that have a risk for future caries (Hiremath, 2011).

Dental recall in Pakistan is usually based on the fixed or 6 months recall visits or problem-oriented visits. In problem-oriented visits, the patient usually shows up at the dental clinic when they experience unbearable pain or difficulty in eating. These visits are more common in developing nations due to the false beliefs regarding oral health such as brushing is sufficient to maintain oral hygiene, extraction is the ultimate remedy, and that scaling can cause tooth loss. On the other hand, fixed or 6 months recall for every individual is not appropriate because there are variations in caries susceptibility and caries progression rate amongst patients (Clarkson et al., 2009). The other concerns to the use of the 6-month recall are high cost, change in disease epidemiology and the misuse of scarce resources (Sheiham, 2000; Tan et al., 2006). It has further been observed that the fixed recalls interval can expose patients to unnecessary dental treatment (Pitts, 2009). Moreover, the low mean DMFT score of 1.2 to 2.5 in Pakistani 12-year-old children suggests a slow caries progression, which makes the traditional six-month recall interval inappropriate for the caries management of this population.

The rational approach to overcome the above problems is to adopt the risk-based recall method. The primary purpose of risk-based recalls are to prevent disease, to detect early any newly developed disease, and to determine the subsequent recall interval period for patients according to their caries risk (Clarkson et al., 2009; Riley et al., 2013). Moreover, risk-based recalls are beneficial when resources are scarce (Riley et al., 2013) and the method enhances the function of the health care system to administer care for individuals at significant risk of oral disease (Institute of Medicine and National Research Council, 2011). The adoption of risk-based recall requires valid and reliable risk assessment tools and caries measuring systems in Pakistan. Such systems can provide data that can assist clinicians to detect decay at any stage (initial enamel lesion to established decay), identify the risk level of a patient, plan recall interval in accordance to the risk level, and to select appropriate treatment procedures for the respective symptoms.

1.1 Aim

This study aims to recommend an appropriate recall interval period for caries management among 11-12-year Pakistani school children.

1.2 Objectives

1. To determine the caries risk levels using reduced Cariogram and caries risk predictors in 11-12-year-old Pakistani school children.
2. To assess the agreement between the WHO and the modified ICDAS methods on caries detection rate.
3. To determine the predictability of reduced Cariogram by comparing the caries risk profile established at baseline with the caries increment on follow up at 6, 12 and 18th month.
4. To determine the rate of caries progression over an 18-month period using the WHO and the modified ICDAS methods to recommend the appropriate dental recall interval.

1.3 Null Hypothesis

The null hypotheses for this study is:

Based on caries progression rate, caries recall interval for 11-12-year-old Pakistani children, regardless of their caries risk status, is 6 months.

CHAPTER 2: LITERATURE REVIEW

This chapter starts by reviewing the literature concerning dental recall intervals such as its definition, the different types of recall visit and its purpose, proposed recall interval, and factors affecting recall interval. It will then discuss the limitation and benefits of the currently used six-month recall interval, and the rationale for prescribing the recall intervals by risk levels. This section then reviews the published evidence regarding caries risk assessments models their validity and reliability, caries diagnosis, additional diagnostic tools, dental caries progression in primary and permanent dentition, issues related to caries measurement and missing data. The factors which favour the adoption of a risk-based approach for the management of dental caries among Pakistani school going children are then discussed, and these include the limitations of the healthcare system, the prevalence of dental caries, access to fluoride and pattern of sugar consumption.

This literature review was prepared by using a conventional search strategy using different databases such as PubMed, ProQuest, OVID, Medline, Ebasco, Google scholar, ResearchGate for literature search. A 'citation searching' technique was also used where leads were followed from useful and prominent articles, books and reading materials. The access to the database, as mentioned earlier, was gained from the University Malaya library. The search was conducted from January 2015 to November 2018. The terms used to search the literature were 'caries risk, risk assessment, recall interval, predictors of caries, fixed recall interval, caries increment, caries progression, caries increment rate, caries increment in Pakistani children, fluoride in Pakistan, water fluoridation in Pakistan, caries increment in 12-year-old children, risk assessment tools, Cariogram, reduced Cariogram'

The lack of systematic structured approach adopted also might not support a comprehensive literature review as some important materials such as government, community organisations and institutions documents may be overlooked as they may not be indexed in these databases. Furthermore, the search was also limited to journals in some specific language ie English language subscribed by the University of Malaya's library which further impose limits in the search strategy.

2.1 Dental recall

A dental recall examination or visit is referred to as “the scheduled appearance of a patient, previously examined in better oral health” (Riley et al., 2013). However, there is no standard definition of a recall visit. The United Kingdom (UK) National Health Service (2002) defines dental recall visit as activities which include clinical examination, provision oral health advice, and writing of clinical report.

The dental check-ups on recall visits are planned to detect early sign and symptoms of oral diseases, to provide advice directed towards the prevention of oral diseases, to provide preventive care, to identify intraoral indicators of systemic disorders, to strengthening the expert advice to enhance patient compliance and to maintain oral health (Frame 2000; Deep, 2000; Boehmer, 2001; Elley et al., 2001; Conway, 2002; Jones et al., 2013). It is the period between two successive routine oral examinations, usually defines in months or years (Riley et al., 2013). Traditionally, the recall interval between two dental examinations recommended by oral health practitioners is six months. Dental recall interval period varies between different countries and agencies. For example, initially in the United Kingdom, the standard interval period prescribed by National Health Services was six months. However, in light of current evidence, the minimum period between recall visits advocated is 3 to 12 months for patients under 18 years old; and 3 to 24 months period for those above 18 years old, depending on their oral health needs (National Collaborating Centre for Acute Care, 2004). In Norway, the customary interval period advocated is one year (Clarkson et al., 2009; Patel et al., 2010; Riley et al., 2013). In the case of Finland, it has been suggested that the period between recall examinations for children can be extended up to 1.5-2 years (Lahti et al., 2001). In the United States, the standard recall interval period for low-risk subjects is from 12 to 24 months. On the other hand, in developing countries, the traditional 6-month recall interval is still very much in practice (Teich, 2013).

It is suggested that the recall interval period between dental examinations must be designed according to the patient needs and risk indicators, because some individuals may need check-ups and precautionary treatment more or less regularly than six months (Peterson, 2003; Clarkson, 2009; American Academy of Paediatric Dentistry, 2014). The risk-based approach for selecting recall interval period has been adopted in several countries such as in the United States. In Australia, the school dental service has implemented a recall system based on the dentist's evaluation of an individual's risk (Riordan, 1997; Lam et al., 2012). In England and Wales, the National Institute for Health and Care Excellence (NICE) has prescribed that the recall interval period must be designed separately for every individual according to the assessment of disease level (National Collaborating Centre for Acute Care, 2004).

2.2 Factors influencing the recall interval

The assigning of proper recall interval is not an easy task and requires a combination of clinical knowledge and scientific evidence concerning patient oral and general health (Clarkson et al., 2009; National Collaborating Centre for Acute Care, 2004). Several elements in current risk evaluating guidelines can impact on recall interval such as diet, microflora and susceptible host, with a mix of social, behavioural, cultural, clinical, environmental factors and protective behaviours (National Collaborating Centre for Acute Care, 2004; American Academy of Paediatric Dentistry, 2014; Advantage Dental Services, 2014).

An essential tool to forecast caries risk is the previous experience of the disease. Previous caries risk experience can impact on the duration of the recall interval because it has a high degree of caries predictive ability (Fontana & Zero, 2006). It is however not useful in defining the caries risk of young children because risk evaluation is mandatory before the occurrence of dental decay. Hence, the presence of white spot lesions in children should be considered at high risk for caries because initial lesions are markers of caries activity (Fontana & Zero, 2006; American Academy of Paediatric Dentistry, 2014). However, previous caries experience is not a causal factor. Caries progression and regression depend on the presence or absence of the modifiable factors such as bacterial count in saliva and plaque, intake of cariogenic food and protective such as the presence of fluoride, and fissure sealants (Petersson et al., 2002).

The level of caries risk at an individual level can be used to determine the recall interval. It has been recommended that for individuals with low caries risk, recall interval can be extended between 12 to 24 months; and for those at medium and high caries risk, the recommended recall intervals are 6-12 months and 3-6 months respectively (American Academy of Paediatric Dentistry, 2016; Pitts et al., 2014). The six-month recall interval prescribed in the above guidelines may be applicable for population residing in areas with sufficient resources. On the other hand, extended recall interval of 12 months can be use for population residing in areas with limited resources and insufficient oral health workforce. Nevertheless, the extended recall interval must not be applied for individuals with high level of caries risk regardless of where they reside. Factors such as caries experience, availability of resources and distribution of the oral health workforce must be considered when deciding the appropriate recall interval.

The age of the target population has an impact on the interval between each recall. In young adults, the oral diseases are less evident, which signify that fewer visits to the dentist are appropriate. On the other hand, oral conditions which are more apparent in older adults in the form of a large number of untreated teeth, high level of tooth loss etc., imply that recall interval for them should be shorter (Petersen &

Yamamoto, 2005). The rate of disease progression also varies among individuals of different ages. For example, evidence shows that the caries spread is rapid in primary dentition compared to the young adult with permanent dentition (Fejerskov, & Kidd, 2008). Up to some extent, this shows that the recall interval can also be designed according to the age cohorts (Celeste & Nadanovsky, 2010).

It is essential to consider the progression rate of caries before designing a recall interval period and preventive strategies (Sheiham & Sabbah, 2010). The progression rate of oral disease for every individual and between lesions is different (National Collaborating Centre for Acute Care, 2004). Several factors which can play a role in the prediction and progression of caries include diet, dental plaque, access to care, baseline caries of children caregivers, and caregivers' dental fatalism and dental decay in parents (National Collaborating Centre for Acute Care, 2004; Southward, et al. 2008; Thitasomakul, 2009; American Academy of Paediatric Dentistry, 2014; Advantage Dental Services, 2014). Moreover, other factors such as mothers' education level, family income, and bottle-feeding habit are also related to the development of dental decay in 24–36-month-old children and can play a role in caries progression (Fejerskov, & Kidd, 2008; Ghom, 2008; Ismail et al., 2009; Karl et al., 2014).

Social variables also need to be taken into consideration because they can assist in the identification of caries risk level of an individual. Socioeconomic status is another major factor which can cause an alteration in the frequency of recall intervals because it can forecast dental caries (National Institutes of Health, 2001). In addition to that, the availability of regular periodic care can influence the frequency of recall interval because routine care can promote good oral health (National Collaborating Centre for Acute Care, 2004; Nowak & Casamassimo, 2002; American Academy of Paediatric Dentistry, 2014; Advantage Dental Services, 2014), hence the availability of regular care may signify the need to increase the time between recall visits.

The frequency of sugary intake is another factor which can change the regularity of recalls. Dental caries is a condition which can cause by a single specific factor which is free sugars (Sheiham, 1987). According to Sheiham, (1987) the only significant factor that determines the caries process in practice is sugars. Sugar intake of less than four times a day is linked with a lower caries experience compared to sugar intake more than four times per day. The high frequency of sugar intake can cause a rapid decline in pH of dental plaque for an extended period and delay the active clearance period which can result in high risk of initial enamel dissolution (Holbrook et al., 1995; Hashizume et al., 2011; Limeback et al., 2012; Viswanath et al., 2014). Moreover, the amount of sugar consumed is also related to caries occurrence. It is reported that among children there is a log-linear relationship in caries occurrence rate even at the sugar intake of 2kg/year (Sheiham & James, 2014b). In addition to that among 11-15-year-old children, the consumption of 5g/day can cause a 1% increase in caries occurrence even in the presence of fluoride (Sheiham & James, 2014b). However, sugar intake cannot play a sole role in caries occurrence. As dental caries is a multi-factorial disease, the interaction of factors such as bacteria, carbohydrates, poor oral hygiene, compromised tooth surfaces, access to care, and social variables should be assessed to determine future caries occurrence (Heymann et al., 2013).

Fluoride has been identified as one of the main factors of declining caries. The optimum fluoride level required in drinking water for caries prevention is 0.7– 1.2 ppm (Mumtaz, 2007). Access to fluoride can impact on the frequency and the time between recall intervals. (Sheiham, 2001; Fontana & Zero, 2006; Singh et al., 2003). However, recent evidence indicates that even in the presence of fluoride, if the sugar intake is high, dental caries can still occur (Ruottinen et al., 2004; Masson et al., 2010). Thus, merely using data on access to fluoride to plan for recall interval is not sufficient. Practical strategies are also needed to decrease the frequency and amount of sugar consumption

(Sheiham & James, 2014). Consequently, the reduction in sugar consumption in combination with the fluoride will have a greater impact on the frequency of dental recall.

Countries around the world have different types of healthcare systems. In some countries, the public sector dominates the health system. On the other hand, some nations depend on private health sector with different methods of financing to render health services (Peterson, 2003). Both systems have the potentials to impact on the duration of the recall interval. In the case of private dental care, the duration of the recall can be affected by the ability of individuals to pay for services. However, private healthcare provider is less focus on prevention. Evidence showed that in the private health care system, the practitioners have more tendencies to prescribe unnecessary procedures and are more focused towards cost and price (Muhuri et al., 1996; Siddiqi et al. 2001; Harding & Preker, 2003). The factors mentioned above can impact on the recall interval period and frequency of recall visits. On the other hand, in the public health system, there are factors which can affect the recall interval period and frequency of recall visits such as accessibility of care, longer waiting times, lack of adequate workforce, less flexible working hours in the public sector, and more emphasis on preventive health services (Brugha & Zwi, 1998; Harding & Preker, 2003; Basu et al., 2012).

The majority of developing countries have a mix health care system. In a mix health care system, the private out of pocket payment system and the government-funded health care system coexist together. Mix health care systems usually developed due to the lack of funding and low incentives for the public health system which compromised the quality and equity (Nishtar, 2010). Secondly, in mix health care system the workforce is more attracted to the private health sector due to the better incentives which consequently reduces the productivity of the government-funded health system (Nishtar, 2010). The less developed and poorly maintained public health system force users to pay the high cost for health services delivered by the private sector, which is a routine in developing countries (Srivastava et al., 2014). Moreover, private insurance in mix health care systems has promoted the trend of high utilisation of dental services to benefit the dentist and the insurance company (Srivastava et al., 2014). High utilisation of dental services can cause reduce timing of the recall interval.

Lack of adequate oral health workforce can directly impact on health system functioning, and population health outcomes (Bronkhorst, 2001). In addition to that, the lack of an adequate health workforce can cause delays in providing emergency care and long waiting times for scheduled services. On the other hand, extra workload and more working hours can reduce the operational productivity of the workforce and reduce quality (Parkash et al., 2006). The lack of adequate oral health workforce can also impact on the timing of the recall interval.

2.3 Types of dental recall

According to Mettes et al. (2005), there are two main types of dental recall. The fixed recall has the same period of the interval for all patients, and the individualised recall is based on the level of disease risk. Other types or terms of recalls have also been reported in the literature with a certain degree of overlaps such as:

1. Short term and long-term recalls
2. Problem-oriented visits
3. Fixed recall
4. Recall intervals based on age groups
5. Recall intervals for secondary care
6. Recall associated with specific disease progression
7. Risk-based Recalls
8. Recall for primary and secondary care

2.3.1 Short term and long-term recall

Short recalls have a shorter interval between examinations. Rapid recall or regular oral examination may improve oral health by multiplying the periodicity with which the dentition status of an individual is evaluated and checked. Immediate care in the short term recalls impact positively on the progression of an illness. On the other hand, the brief recall interval periods can increase the probability of over-diagnosis, unnecessary treatment and a high cost of care (Riley et al., 2013).

The long-term recall has extended period between two examinations. Long-term recalls are associated with compromised oral health due to the decrease periodicity of preventive care and deferring of diagnosis which consequently leads to high priced care. In extended intervals, it is difficult to determine the speed of progression and changes in disease activity precisely and may therefore cause a high level of ambiguity in predicting disease. This may be due to the change in lifestyle and behaviour (Fontana & Zero, 2006). However, there are fewer chances of getting over treatment in long-term recalls (Riley et al., 2013).

2.3.2 Problem-oriented visits

This type of appointment is not pre-planned by health practitioners. In this case, patient usually shows up at the dental clinic when they experience unbearable pain or difficulty in eating. The trend of problem-oriented visits is more common in developing nations due to the false beliefs regarding oral health; for example, brushing is sufficient to maintain oral hygiene, extraction is the ultimate remedy, and that scaling can cause tooth loss. Consequently, this prevents individuals to show up at dental clinics and postpone the necessary treatment which can exacerbate the problem (Khan et al., 2012).

2.3.3 Fixed recall

In 1900, the American Dental Association issued the first brochure endorsing visiting the dentist at least twice a year and recommended that recall visit must be more frequent in the case of unhealthy dentition (Patel et al., 2010; Teich, 2013). Dentifrice advertisement popularised this view in 1920 and 1930 (Clarkson et al., 2009). Later on, the dental insurance industry embraces the concept of six-month recall visits (Teich, 2013).

The intervals in fixed recalls are at different time lengths such as six months, 12 months, and 24 months. Currently, many dentists still prefer and recommend biannual dental checks as a standard (Mettes et al., 2005; Clarkson et al., 2009; Riley et al., 2013). Fixed recalls consume less time and provide more time to perform dental practice because biannual dental check-ups are based on a ten-minute intraoral examination, scaling, and polishing regardless of the patients' oral health (Mettes, 2005; Mettes et al., 2007). The fixed recall intervals are therefore more financially rewarding to a dentist (Benn, 2002). However, there is no substantial evidence to support the practice of fixed or 6-month recall (Clarkson et al., 2009).

The fixed recalls method is ineffective in the diagnosis and management of caries because there are variations in caries susceptibility and in caries progression rate amongst patients (Clarkson et al., 2009). Risk assessment in fixed recalls is carried out by observations and previous experiences (Riley et al., 2013). However, calculation of risk requires qualitative and quantitative assessments to measure the likelihood that specific events will occur (American Academy of Periodontology, 2008). Also, objections to the 6-month recall include their high cost, change in disease epidemiology and the misuse of scarce resources (Sheiham, 2000; Tan et al., 2006). It has further been observed that fixed recalls can expose patients to unnecessary dental treatment (Pitts, 2009).

2.3.4 Recall based on age groups

The guideline by NICE recommended the extension of interval for the individual's age 18 years or above is 24 months. The frequency of recall intervals is 3, 6, 9, 12, 15, 18 and 24 months. On the other hand, in cases of individuals less than 18 years, the maximum interval is 12 months, and the frequency of recall intervals are 3, 6, 9, 12 months (National Collaborating Centre for Acute Care, 2004; Clarkson et al., 2009). The above guidelines are based on sensitivity; the participants identified with high caries risk will receive a detailed assessment considering factors such as age, behaviour, systemic condition to create a treatment plan. These recommendations were made using category I- IV evidence (National Collaborating Centre for Acute Care, 2004).

2.3.5 Recall for secondary care

The recall for secondary care is designed to cater some particular reasons such as disease management, the process of treatment, emergency dental interventions, or episodes of specialised care, which is outside the scope of oral health review (National Collaborating Centre for Acute Care, 2004).

2.3.6 Recall interval associated with specific disease progression

These recall intervals are according to the progression of a disease. For example, caries progression is rapid in children and adolescents, as compared to adults. On the other hand, caries advancement is faster in the primary teeth as compared to permanent dentition (Fejerskov & Kidd, 2008). Thus, a shorter recall interval can be designed for children whose primary dentition are still present.

2.3.7 Recall interval based on risk assessment

The risk-based recalls are designed after assessing the patient's risk of developing future oral disease. During the early 1980s, it was proposed that dental recalls should be based on caries risk, but due to the absence of protocols for evaluating the risk and established recall schedule, the practitioner had to depend on subjective evaluation (Cohen et al., 1983). With time, more evidence about the need of the risk-based schedules begins to emerge such as fixed recalls are ineffective for caries management, variation in caries susceptibility and caries progression rates within the population which causes the debates to determine risk and recall interval to continue.

The primary focus of risk-based recalls are disease prevention, early detection of any newly developed disease, to determine the subsequent recall interval period for patients according to their caries risk (Clarkson et al., 2009; Riley et al., 2013). Risk-based recalls are beneficial when resources are scarce (Riley et al., 2013) and enhance the function of the health care system to administer care for individuals at significant risk of oral disease (Institute of Medicine and National Research Council, 2011). The adoption of risk-based recalls provides more opportunity of getting preventive treatment to the individuals in genuine need (Batchelor & Sheiham, 2002).

The risk-based approach for selecting the recall interval period has been adopted in several countries, such as in the United States. In Australia, the school dental service has implemented a recall system based on the dentist's evaluation of an individual's risk (Riordan, 1997; Lam et al., 2012). In England and Wales, the National Institute for Health and Care Excellence (NICE) has prescribed that the recall interval period must be designed separately for every individual according to the assessment of disease level (National Collaborating Centre for Acute Care, 2004). According to the NICE guidelines for low-risk individuals, the recall interval can be extended from 12-24 months. On the other hand, for individuals with risk recall interval can be extended from 3 months to 12 months (National Collaborating Centre for Acute Care, 2004). These recall intervals are not fixed and can be modified if the threshold of risk level changes and move from low to higher risk shorter interval can be assigned (Brocklehurst et al. 2011).

An audit project to categorise patients according to risk found that changing the nature of the recall interval from fixed to risk-based can lead to healthy dialogue about the aetiology of dental diseases between patient and doctor (Gibson & Moosaje, 2008). Consequently, the discussion results in improvement of the patient's health. In risk-based recall, there is a chance of getting over treatment in the case of attendance with more than one visit in a single year (Patel et al., 2010). Incorrect estimation of individual risk can lead to faulty recall interval resulting in several patients getting their check-up too early, while many individuals can be too late for early treatment. In addition to that, risk-based recall can be exhaustive, especially if it involves periodontal screening, risk assessment, and record keeping. Also, explicit consultation with the patient can extend the time required for routine oral examination. Lastly, it provides less time to perform dental practice (Mettes et al., 2005).

2.3.8 Recall for primary and secondary care

This type differs from the recall interval for secondary care in which only secondary care is dispensed. These types of recalls are defined according to the type of care provided namely primary or secondary. In these recalls, the central component is advice which can impact on individuals' behaviour to prevent the occurrence of oral disease. On the other hand, the focus of secondary care is on limiting the illness at an early stage to avoid further progression (Deep, 2000).

2.4 Dental caries

Dental caries is a chronic, transmissible and multifactorial disease of dental hard tissue having different phases of remineralisation and demineralisation consequently results in the loss of tooth structure (Kidd, 2005). Globally, 60%-90% of school going children has experienced this disease and the caries levels for 12-year-old are increasing constantly in developing countries (Bagramin et al., 2009; Pai et al., 2018). Dental caries can impact on the quality of life by restricting the routine life activities such as loss of school, working hour, reduce social involvement, decrease functional activities, and disturb emotional life (Ali et al., 2012).

Dental caries is caused by the interaction of bacteria (biofilm), carbohydrates, host and time. In addition to the above factors, several modifying risk factors are involved in caries development as shown in Figure 2.1 (Heymann et al., 2013). The bacteria responsible for dental decay are transmissible from mothers to babies in early life and colonise the soft tissue before the eruption of teeth and colonise the teeth as they erupt (Berkowitz, 1996; Berkowitz, 2003; Featherstone, 2008).

Recent metatranscriptomic data reveals that different microorganisms colonize carious lesion according to its severity, from early enamel lesion to established decay, in a single tooth (Simon & Mira, 2015). The data reveals that the most dominant bacteria in dental caries is Streptococcus mutans. Veillonella, Rothia, and Leptotrichia have been found to be associated with enamel caries. For dentinal caries, Streptococcus sanguinis, Atopobium, Schlegelella, Pseudoramibacter, and Lactobacillus act as the main players (Simon & Mira, 2015). Microorganisms on the surface of enamel contains mostly sugar fermenting genes and adhesion molecules. On the other hand, microorganisms in dentinal cavities contain different types of enzymes to metabolize human glycans (Simon & Mira, 2015).

The cariogenic bacteria produce lactic acid by metabolising the fermentable carbohydrates. The lactic acid is capable of dissolving the enamel and dentin resulting in the cavity formation. This process takes months and years to cause cavitation. White spot lesion is the stage at which dental caries begins. However, this is a reversible stage, if therapeutic measures are applied (Featherstone, 2008). The process of dental caries is composed of phases of demineralisation and remineralisation. Demineralisation began in the crystals of enamel and dentin and continued towards the cavitation if not stopped. The incorporation of fluoride ions into the crystals can halt and reverse demineralisation (Krasse, 1988; Featherstone, 2008). The second factor is saliva, which can reduce the demineralisation process by buffering the acid produced by the bacteria and promotes remineralisation by providing calcium and phosphates.

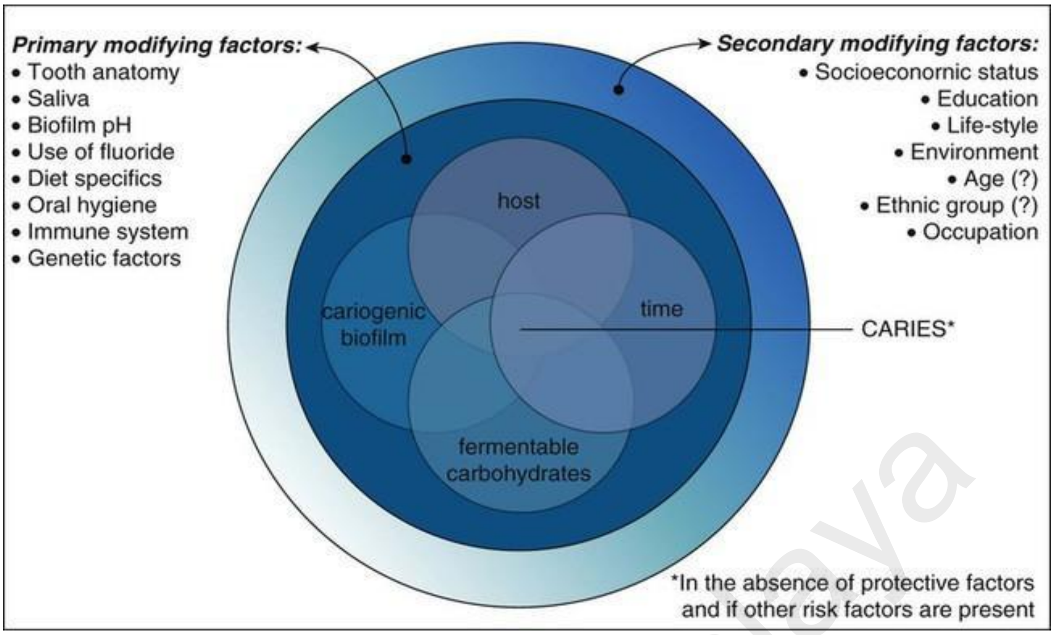


Figure 2.1: Modifying risk factors involve in caries development (Adopted from Heymann et al., 2013)

Remineralisation of initial enamel lesion occurs in the presence of calcium, phosphate and fluoride ions. Remineralisation forms a new surface on the crystal remnants survived in the demineralisation stage. These crystals are more resistant to the demineralisation compared to the original mineral (Lamkin & Oppenheim, 1993; Featherstone, 2008). The loss of tooth structure and repairing of enamel continues in the oral cavity as long as caries causing microbes, saliva and fermentable carbohydrates are present in the oral cavity. The process of demineralisation and remineralisation depends on the balance between the protective and pathological factors as shown in Figure 2.2 (Featherstone, 2000; Featherstone, 2004).

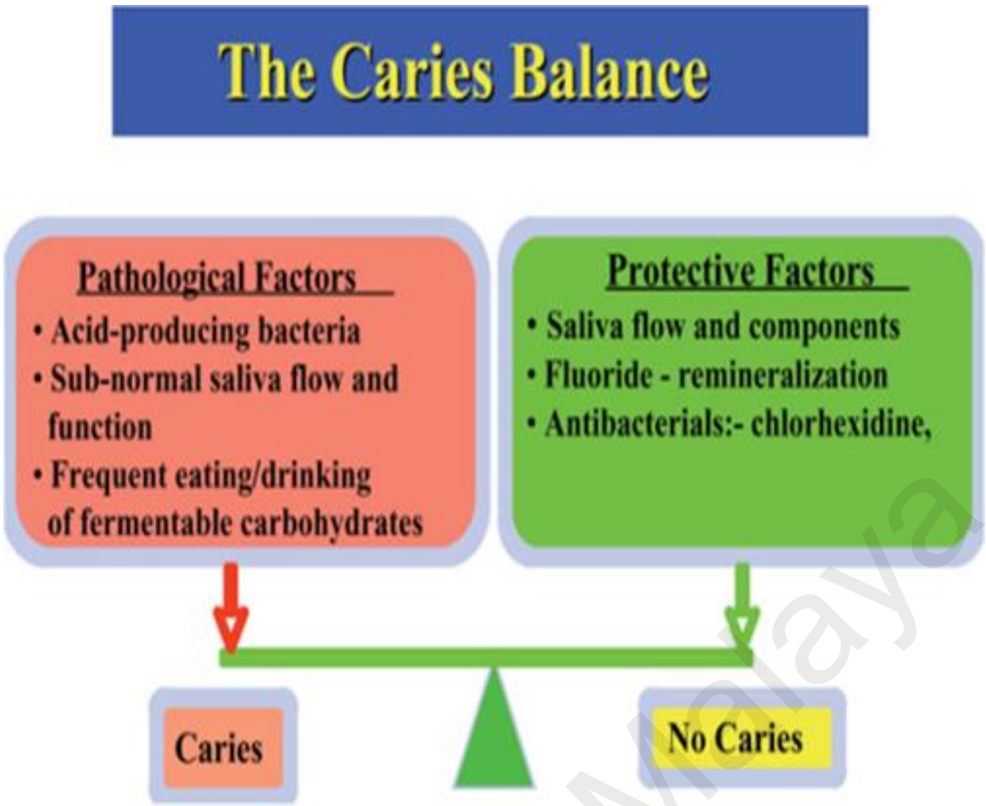


Figure 2.2: The caries balance between the protective and pathological factors (adapted from Featherstone, 2004).

2.5 Caries progression

Data on the life history of dental caries in teeth can aid in designing a treatment plan for individuals. The rate of caries progression through enamel into dentine plays a vital role in determining the frequency of dental recalls (Sheiham & Sabah, 2010). The existing literature has shown a relationship between DMFT and caries progression. When the DMFT score is low, the rates of progression are slower while they are more rapid in a population with higher DMFT scores (Mejare et al., 1999; Lith et al., 2002; Mejare et al., 2004; Sheiham & Sabbah, 2010). Moreover, evidence has shown the relationship between prevalence of caries, and strength of caries attack (DMFT) (McDonald & Sheiham, 1992; Bachelor & Sheiham, 2002; Broadbent et al., 2008). As the prevalence of dental caries falls, the high number of least susceptible sites affected by caries is reduced, while the number of most susceptible sites reduced is small (Sheiham & Sabbah, 2010).

The unusual fact about caries is that it can track individual or group at a later age (Massler et al., 1954; Sheiham & Sabbah, 2010). Masseler et al. (1954) proposed that the severity of caries attack at the specific age if known can help in the prediction of dental caries at a later age. For example, the individual with high caries risk at a certain age would follow a similar chance of caries increment at a later age.

The occurrence of dental caries is symmetrical due to which the probability for caries attack on the right and left side of the mouth and on the posterior teeth of maxilla and mandible is equal (Berman & Slack 1972; Hujoel et al., 1994b; Sheiham & Sabbah, 2010). However, anterior maxillary teeth are more prone to dental caries as compared to the lower anterior teeth. This symmetrical pattern of caries indicates that caries develops in steps, for example, if any tooth in the right quadrant is decayed, so will the tooth in left quadrant (Marthaler, 1966; Berman and Slack, 1972; Poulsen and Horowitz, 1974; Hujoel et al., 1994a; Batchelor & Sheiham, 2004). Symmetrical pattern of caries occurrence has led to the development of a measurement method which proposed the doubling of the score after unilateral intraoral-examination to diminish examination time.

The stepped pattern of dental decay proposes that there are categories of tooth surfaces that have the same ability to resist dental decay. For example, if any tooth surface in a group has a high resistance to decay due to fluoride, the resistance of all other surfaces in a similar group will also be increased.

Batchelor & Sheiham (2004) has identified the hierarchy of tooth surfaces according to their caries susceptibility (from highest to lowest susceptibility).

(1) Bilateral occlusal surfaces of first molars and buccal pits of lower first molars.

(2) Bilateral occlusal surfaces of second molars and buccal surfaces of lower second molars and occlusal surfaces of all second premolars on both sides of the mouth.

(3) Bilateral occlusal surfaces of first premolars, palatal surfaces of upper lateral incisors, proximal surfaces of first molars, lingual surfaces of lower first molars and buccal surfaces of upper first molars and palatal surfaces of upper second molars.

(4) All proximal surfaces of second premolars, upper first premolars, mesial and lingual surfaces of lower second molars, distal and buccal surfaces of upper second molars, proximal surfaces of upper central incisors, upper and lower lateral incisors, lower central incisors and proximal surfaces of upper canines, and second molars.

(5) All surfaces of lower canines, buccal and mesial aspects of upper canines, all smooth and proximal surfaces of lower first premolars, smooth surfaces of lower central incisors, proximal surfaces of lateral incisors.

The evidence suggests that caries progression is faster in the primary dentition (Fejerskov, & Kidd, 2008). The morphology of primary teeth is different from permanent dentitions. The enamel and dentine of primary teeth are less thick as compared to their replacements and have large pulp chamber with pulp horns compared to permanent teeth (Gulabivala, & Ling, 2014). Moreover, primary enamel is more porous and contains low mineral content and has more carbonates, fewer phosphates, and calcium (Amaechi et al., 1999; Lippert et al., 2004; Correr et al., 2007).

The most common surfaces affected by caries in the primary dentition are occlusal surfaces of second molar and distal surfaces of the first molar (Lueckel et al., 2013). It is observed that the development of initial carious lesion on a sound proximal surface is slow during the mixed dentition stage (Vanderas et al., 2003). In the case of 5 years old children, the second molar has high experience rate of caries (Lueckel et al., 2013). A longitudinal study by Warren et al., (2006) showed that in primary dentition, 30% of pits and fissure lesions progress to cavities. On the other hand, very few non-cavitated lesions on smooth surfaces progress to cavitation (Warren et al., 2006).

It has been reported that the rate of caries progression is 1.6 times higher in primary molar as compared to permanent molar (Lueckel et al., 2013) due to the reduced enamel thickness in proximal surfaces of deciduous teeth (Fejerskov, & Kidd, 2008). The frequency of caries advancement from enamel to dentin in primary molar is 2.5 years (Koch, & Poulsen, 2009). In primary teeth, the time for progression of the non-cavitated carious lesion to a cavitated lesion on a smooth surface is 18 ± 6 months. In the case of an occlusal surface, lesion develops in less time compared to the smooth surface (Fejerskov, & Kidd, 2008; Heymann et al., 2013).

For permanent dentition, different tooth sites have different caries susceptibility. The occlusal surfaces of the posterior teeth and buccal pits of lower first molar have a high risk of caries development, followed by the contact areas of posterior teeth. Evidences show that if all first molars have dental caries, the chance of caries development in a second molar is high because occlusal and proximal surfaces of the second molar are second most susceptible sites. However, in the case of elevated DMFS scores, the vulnerable sites are the mesial surface of upper molars as compared to the lower proximal surfaces (Bachelor & Sheiham, 2002; Sheiham & Sabbah, 2010).

Caries progression in enamel is fast in newly erupted permanent dentition, especially the mesial surface of a permanent molar. This is due to the incomplete maturation of enamel in the first post-eruptive year, the large diameter of dentinal tubules, and lack of remineralisation due to the frequent sweet consumption (Schuurs, 2013). The occurrence of a carious lesion in approximal surfaces of permanent teeth is rapid but, the lesion advancement is slow and often revert (Pitts, 1983; Arrow, 2007). Proximal carious lesion takes at least three years from enamel to dentin (Pitts, 1983; Arrow, 2007). The distal surfaces of permanent lower molar and second premolar have a high risk for the rapid advancement of dental decay. The rate of caries advancement in the tooth surfaces differs by DMFT levels. (Lawrence et al., 1997; Mejare et al., 1998; Lith et al., 2002; Mejare et al., 2004; Fejerskov, & Kidd, 2008; Koch, & Poulsen, 2009).

The usual time caries takes to advance in permanent teeth through an outer surface of enamel to inner enamel is 54 months; from enamel to dentin is 34 months and progression in dentine takes 8-9 months (Arrow, 2007; Koch, & Poulsen, 2009). However, for a patient at high or very high risk of caries, the lesions may progress faster, and cavitation may occur sooner. In dentine, the progression of dental caries is equally higher in both primary and permanent teeth. In a population with low caries prevalence, the median survival time for a carious lesion in permanent teeth at the enamel-dentine border is three years before it reaches the outer half of dentine, however, some lesion progress faster than that (Fejerskov, & Kidd, 2008; Koch, & Poulsen, 2009; Sheiham & Sabbah, 2010; Lueckel et al., 2013).

The mean DMFT scores, variation in caries development on different tooth surfaces and sites, stepped pattern and bilateral occurrence of dental caries and caries progression rates can be used to determine the recall interval period and to decide appropriate treatment strategies.

2.6 Risk assessment

The chance that specific events will occur during the precise time is known as risk (Reich et al., 1999). In the case of health, the adverse health risk is the likelihood of developing a disease in the near future. Moreover, the development of an infection in human requires contact with factors known as risk factors. If the risk factors are recognised and managed appropriately, this can reduce the chances of disease development (Rose, 1985; Hallett, 2013). Risk management requires an understanding of risk and strategy through which a positive outcome for patients can be achieved. Effective risk management is composed of risk identification, risk assessment, action planning, regular monitoring and review, continuous communication and consultations (Hallett, 2013).

Risk identification is the process of documenting the risk to provide information regarding their presence and effects. Risk assessment is a technique for measuring the level of risk. Action planning is the procedure that deals with policies to reduce risk and its consequences. Continued observation and assessment are required to guarantee that we are doing our job correctly to recognise new risk factors. Lastly, all stakeholders must be involved to ensure the risk process is correct (Hallett, 2013).

Risk assessments can be conducted at the individual or population level. Both use strategies to control diseases that aim 1) to identify the high-risk individual and 2) to limit the incidence of disease in the population (Rose, 1985; Hallett, 2013). The categorising and measuring of the susceptible factors which can cause illnesses is the central part of an individual risk assessment. The fundamental concept of which individual risk assessment works is the equilibrium between attacking agents and human resistance (Featherstone, 2006). On the other hand, population risk assessment models focus on identifying those environmental risk factors that can forecast future disease incidence at a population level, e.g. socioeconomic status (Twetman, & Fontana, 2009). A variable can be considered as a risk factor when it can be used to categorise the population into high and low-risk groups or when it appears before the outcome (Offord & Kraemer, 2000). Risk factors can be classified into 3 main categories. Risk factors that cannot be changed such as age, gender, ethnicity, is known as fixed risk factors. Variable risk factors are those that can be manipulated by using intervention. Risk factors that can be manipulated, and which consequently change the probability of the outcome is known as causal risk factor. Fixed risk factors are used to identify high and low-risk individuals. Interventions used to reduce the incidence of disease must focus on the causal risk factors (Offord & Kraemer, 2000).

There are four identified properties of a risk factor. Risk factors for any disease may not be similar, and the strength of a risk factor varies in different populations. In addition, the risk factors for remission and relapse of the disease are different. The third property is that the frequency of risk factors and its associated outcome must not be similar in a population. Lastly, some risk factors are protective and can improve the chances of positive outcomes (Offord & Kraemer, 2000). The power of a risk factor can be determined by the relative importance of false positive and false negative outcomes and by the after effect of the threshold set to decide the presence of that factor (Offord & Kraemer, 2000).

Risk tends to change with the time for example; patients with active lesion may develop chronic disease, but it is also possible that individuals with no active disease can develop an infection in the future. Change in risk status occurs due to the shift in individual lifestyle, behaviour, diet, oral hygiene habits and stress (Beck et al., 1988; Fontana & Zero, 2006). Therefore, brief predictions of risk (<2 years) are more dependable as compared to the long projections (>5 years) due to the changes in lifestyle which can make a prediction inaccurate (Fontana & Zero, 2006).

2.7 Caries risk

Today, the approach of treating dental caries with surgical restorations has changed. Current knowledge has provided evidence that by altering and modifying the complex dental biofilm and the oral components which favour health, dental caries can be prevented (Young et al., 2007a; Hara & Zero, 2010; Marsh, 2010). The underlying foundation of caries management by risk assessment is to arrest dental caries by diminishing the effect of caries-inducing factors and enhancing the impact of protective elements (Hurlbutt, 2011).

Caries risk assessment is an essential part of patient centred caries management (Tellez et al., 2013). Caries risk assessment is done to evaluate the patient's risk level, plan recall interval, to determine and select diagnostic and treatment procedures, to identify major causative elements, and to investigate the number of new incipient or cavitated lesion. Caries risk assessment is a complicated procedure which involves consideration of several risk factors. For example, diet, microflora, and susceptible host, with a mixture of social, behavioural and cultural agents, management of causative factors of the disease, previous caries experience, and the presence of early enamel lesion are all risk factor for dental caries (Zero et al., 2001; Hallet, 2013; Zukanović, 2013; American Academy of Paediatric Dentistry, 2014). In addition to that, the practitioner's instinct is also considered as an accurate tool to assess risk compared to current diagnostics (Sarmadi et al., 2009; Sanchez et al., 2009; Twetman & Fontana, 2009; Riley et al., 2010). Experienced practitioners often can measure a subject's caries risk with certain precision (60–70%) (Saemundsson, 1996). However, the practitioner's instinct is not a quantifiable measure.

There are three levels of risk namely high, medium and low.

High Risk: The high-risk population is a sample of a community which is considered at a higher chance of developing the disease compared to the people at medium risk (Reich et al., 1999). The factors which are present singly or together can contribute towards average to high risk are the growth of new carious lesions, existing active lesions, restoration due to active disease and due to the 1-year gap between examinations (Fontana & Zero, 2006).

Medium Risk: The differentiation between medium and high-risk population can be done by using factors such as the time lesion takes to develop and the number and severity of the lesions. The elements which can identify the medium to low-risk patients are no dental decay between previous and current examination, plaque levels, intake of sugar, salivary flow, access to fluoride, change behaviour and physical disability (Fontana & Zero, 2006).

Low risk: The following factors if present in combination or alone can be used to identify low-risk patients. They are the absence of active carious lesions, dental filling which was performed five years back, and negligible associated factors. If no activity of caries is observed between longer intervals, the patient can be identified as low risk (Fontana & Zero, 2006).

It is simple to identify individuals with high and low caries risk rather than identifying individuals with medium caries risk. The recognition of average risk individual is complicated because they show little or no caries development for longer duration and unexpected occurrence of the carious lesion (Kraglund, 2009). Caries risk assessment assists a clinician in providing proper prevention strategies and to reduce the unnecessary resource utilisation (Kraglund, 2009). By corresponding the patient's risk level to the suggested preventive therapy, the clinician has high chances of positively affecting the patient's oral health (Stamm et al., 1991; Kraglund, 2009).

2.8 Caries risk assessment models

There are limited numbers of long-term prospective studies available to support the use of caries risk assessment models. However, experts claim that dental caries risk assessment is an integral part of minimal intervention dentistry and a new standard for caries management (Fejerskov, 2004; Young et al., 2007a; Kidd, 2011; Nowak, 2011). In current dental and medical practice, the risk assessment guideline is for

1. Acquiring precise knowledge regarding patient disease susceptibility and preventive steps to prevent its occurrence instead of curing the consequences of the condition.
2. It aids in the identification of disease factors for a specific individual, predicts disease progression or stabilisation.
3. It plays an essential role in delivering knowledge regarding treatment approaches in a language that is accessible to practitioners and advantageous for the patient and practitioner.
4. Supports health practitioners to design a suitable recall interval for a patient by their level of risk of developing the disease in future (Woolf et al., 1999; Ollenschläger et al., 2004; Watt, 2005; Berg, 2007; Hallet, 2013; American Academy of Paediatric Dentistry, 2014).

The current challenge for researchers is to develop precise and dependable markers for the future decay experience that can be utilised rapidly without any cost (Hallet, 2013). Brocklehurst et al. (2011) describes the properties of the ideal risk assessment tool, which includes low cost, simple outcomes, time-saving, acceptable to both dentist and patient, acceptable accuracy until the next review, and evidence-based. The properties which ensure that accurate results can be extracted from any risk assessment tools are validity (accuracy), reliability (precision) and responsiveness (Peterson et al., (2010a; Christian et al., 2018).

Validity is the power of a tool to quantify what it is supposed to measure. Predictability is the power of a device to forecast the future health of the individual. Reliability is the ability of a model to provide the same results if repeatedly applied in constant conditions (Fayers & Machin, 2007). Reliability is the essential component which is required for a valid measure, but it is also possible that a reliable question is not valid (Fayers & Machin, 2013).

Validity assessments is composed of content, construct and criterion validity (Christian et al., 2018). The validity of a caries risk assessment model is estimated by its sensitivity (SE) and specificity (SP). Sensitivity (SE) is the power of a risk assessment tool to identify people with high risk correctly. Specificity (SP) is the power of a risk assessment tool to recognise people with reduced risk accurately. A risk assessment tool with a total SP and SE score of 160% is practically useful (Stamm et al., 1988; Zero et al., 2001; Gao et al., 2013). Regrettably, only a few caries risk assessment tool able to achieve the value of 160%. Both measures are commonly used in dental research to evaluate the accuracy of a screening test. The sensitivity and specificity can measure the predictive power of any model. Recent evidence from the systematic review conducted by Christian et al., 2018, reports that only the criterion validity of current available caries risk assessment tools is reported in available studies. Construct and content validity of the CRA tools are poorly reported.

On the other hand, reliability assessment is based on internal consistency and measurement error. Similarly, Christian et al., 2018, also reports that the reliability of the CRA tools is also underreported by systematic reviews.

As far, as the predictability of risk model is concerned, prediction models based on one or two risk factors such as previous caries experience cannot accurately estimate dental caries in the future. The rationale behind not selecting previous caries experience as the only predictor of future dental caries is that it requires a clinician to wait until the disease manifests itself before they can predict it accurately (Steiner et al., 1992; Bartthal & Ericsson, 1994; Reich et al., 1999, Fontana & Zero, 2006). Combination of multiple factors in the caries risk assessment model has shown superior results in caries prediction (Beck et al., 1992; Tinanoff, 1995; Kraglund, 2009). This effect is due to the multifactorial nature of dental caries (Fontana & Zero, 2006).

Caries risk assessment tool with high specificity may be useful for screening at a public health level to avoid false positive results. Health administration does not prefer a high count of false positive, which can expose patients to unnecessary treatment. It is critical in settings where resources are limited, and recommended therapy is invasive and costly (Douglas, 1998; Zero et al., 2001; Kraglund, 2009).

On the other hand, it may be beneficial from the ethical and financial point of view to raise the sensitivity of a risk assessment tool to avoid false negatives results. The higher number of false negative conclusions can expose patients to unnecessary treatment in future which may be costly and painful due to the progression of a disease. Raising the sensitivity of risk assessment tool can cause an increase in false positive results. However, it can expose some patients to unnecessary treatment. If practitioners use appropriate preventive strategy, this will cause very little harm to the patient by not permitting the disease to occur or progress at little cost for preventive treatment (Zero et al., 2001; Kraglund, 2009).

Most of the evidences for current caries risk assessment models are from cross-sectional and longitudinal studies. In cross-sectional studies, risk factors and caries severity relationships are reported by statistical tests, and in longitudinal studies, risk factors are associated with the appearance of a new carious lesion in a particular duration (Peterson et al., 2002). Moreover, the severity of dental decay in cross-sectional studies is defined by previous exposure to risk factors over a period that cannot be evaluated at any single point in time (Tellez et al., 2013).

Caries risk assessment models designed using cross-sectional studies with multivariate regression to identify individual's caries risk status are not able to establish a causal relationship (Tellez et al., 2013). Another shortcoming associated with the regression model is that in the case of different independent factors, the relationship between elements can reduce or limit the power of the model to recognise risk factor (Mendelhall & Sincich, 1996; Tellez et al., 2013).

According to the Swedish Council on Technology Assessment in Health Care, longitudinal studies will be more effective in determining the accuracy of prediction (The Swedish Council on Technology Assessment in Health Care, 2008). Despite the reduced precision, current guidelines are dependable in categorising the patient's risk (The Swedish Council on Technology Assessment in Health Care, 2008; Peterson et al., 2010a). Currently, two types of multivariable caries risk assessment model are available. Algorithms based/Computer-based (Cariogram and Caries risk assessment tool by National University of Singapore or NUS-CRA) and reasoning-based tools (CAT, CAMBRA and risk factors identified by the International Caries Management and Classification System) (Gao et al., 2013). These risk assessment models are made of two variables, risk factors and risk predictors.

An exposure notably associated with the occurrence of disease can be environmental, biologic or lifestyle and is known as a risk factor (Beck, 1998; Rose, 2001; Kraglund, 2009). Risk factors are a component of the causal chain of illness and gathering of information regarding risk factors during risk assessment facilitate practitioner in planning preventive therapy (Powell, 1998; Kraglund, 2009). On the other hand, risk predictors are merely biological markers which provide information related to the disease process but cannot determine the cause of disease. Predictors can be pathological such as previous caries experience, and protective such as access to fluoride (Douglas, 1998; Kraglund, 2009).

There is no ideal risk assessment tool available, and up to some extent there is a chance of error in the prediction of future caries risk inclusive of over and under treatment chances. (Pitts, 1998; Kraglund, 2009) It is essential to think trade-off carefully before considering cut-offs for sensitivity and specificity because there are consequences of having a large number of false positive or false negative results (Hausen, 1997; Kraglund, 2009).

2.8.1 Caries risk assessment tool (CAT)

The American Academy of Paediatrics has introduced the Caries Risk Assessment Tool (CAT) for caries risk assessment of infants, children, and adolescents in 2006. It also includes models of dental caries treatment practices (American Academy of Paediatric Dentistry, 2014). The purpose of this tool was to educate oral health practitioners regarding caries risk assessment in paediatric dentistry and to provide help regarding fluoride, nutritional, and restorative protocols.

CAT is composed of three main factors which are biological, protective and clinical factors. Biological and clinical factors constitute high and medium risk indicators. On the other hand, protective factors represent the low-risk markers. The dental radiographs, saliva testing, and microbial testing are not essential in CAT. The diagnosis of risk level by CAT is based on a preponderance of factors in any of the risk level (low, medium, or high) for an individual. However, clinical judgment may justify the use of one element (e.g., ≥1 interproximal lesion, low salivary flow) in determining overall risk (Zukanović 2013; American Academy of Paediatric Dentistry, 2014). In CAT, the subject is categorised as high risk if any single high-risk indicator is present, and they will be considered as low risk if no high risk or medium risk indicator is present (Tellez et al., 2013) as shown in Table 2.3.

The high-risk indicators are low socioeconomic status, a patient with special health care needs, >1 interproximal lesion, active white spot lesion or enamel defects

(American Academy of Paediatric Dentistry, 2014). The medium risk indicators include immigrant patients, high sugar intake especially those that are taken between meals, the presence of defective restoration, and when no high-risk indicator is present. The low-risk indicators include patients with access to regular dental care and had optimal fluoride in drinking water, patient who brushes teeth daily with fluoridated toothpaste, those who receive topical fluoride from health professionals and take additional home measures (e.g. xylitol, MI pastes, antimicrobial) and those with no medium and high-risk factor is present.

There are limited published data available regarding the caries predictability of CAT (Tellez et al., 2013). Studies conducted by Gao et al. (2013) and Zukanovic (2013) have reported low caries predictability of CAT. It is observed that CAT is unable to record individuals with low risk as compared to other risk levels (Nainar & Straffon, 2005; Gao et al., 2013) because a patient is considered to be at high risk if any single high-risk indicator is present such as low socioeconomic status. It is reported that when low socioeconomic status is included in the risk assessment, the specificity and predictive value of CAT is diminished. However, it is improved when the socioeconomic factor is excluded (Yoon et al., 2012).

A longitudinal study on preschool children to assess the validity of CAT in full and reduced form was conducted by Gao et al. (2013). A total of 544 pre-schoolers of age three years old were enrolled. The result showed that CAT had identified and classified the majority of individuals at high risk, a small proportion at medium risk and no low-risk pre-schoolers. They reported that the specificity and sensitivity of a reduced and full version of CAT have extremely high sensitivity, but low specificity when used with or without socioeconomic risk factors. Gao et al., 2013 reported a poor reliability of this tool Table 2.4.

2.8.2 Caries management by risk assessment (CAMBRA)

The concept of Caries Management by Risk Assessment (CAMBRA) was introduced by an unofficial group known as CAMBRA Coalition which includes different stakeholders (Young et al., 2007). Later, CAMBRA protocols were presented as an official policy in dental education. CAMBRA is an evidence-based method to tackle dental caries at the earliest possible stage (Domejean et al., 2006; Hurbutt, 2011). CAMBRA has also been modified for data collection on school going children, and it is available in electronic version for the management of medically compromised children (Hallett, 2013). CAMBRA is composed of three factors which include disease indicators, biological factors (risk factors) and protective factors.

i. Disease indicators are visible cavities or radiographic penetration of the dentin, radiographic proximal enamel lesions (not in dentin), white spots on smooth surfaces, and restorations in the last three years.

ii. Biological factors are bacterial count measure by culture, amount of plaque on teeth, snack > 3x daily between meals, deep pits and fissures, recreational drug use, inadequate saliva flow by observation or measurement, saliva reducing factors (medications/radiation/systemic), exposed roots, and presence orthodontic appliances.

iii. The protective factors are access to fluoridated water, use of fluoride toothpaste twice daily, use of fluoride mouth rinse (0.05% Naf) daily, fluoride varnish and topical fluoride application in last 6 months, chlorhexidine for previous 6 months, xylitol gum 4x daily previous 6 months, calcium and phosphate paste during previous 6 months and saliva flow (> 1 ml/min stimulated).

The clinical judgment defines the diagnosis of risk level in CAMBRA. However, if any single high-risk factor is present, the individual can be categorised as high risk.

For the desired outcome by CAMBRA guideline, basic knowledge of consultation skills and coordination is required between the patient, office staff, dental assistants, dental hygienists and dentists (Gutowski et al., 2007). In the case of preschool children, it is observed that reduced CAMBRA can identify low-risk participants (Gao et al., 2013). Like CAT, this tool can also overestimate caries risk because it considers an individual at high risk in the case of past caries experience, low socioeconomic status and in the presence of any developmental problems (Gao et al., 2013) Table 2.3.

A retrospective study has been conducted to evaluate the caries predictability of CAMBRA (Domejean et al. 2011). The result showed a significant relationship between visible cavitation, caries radiographic penetration of the dentin and interproximal enamel lesions to the overall caries risk at baseline. At first follow-up, 69% of high-risk individuals were diagnosed with new cavities. Eighty-eight per cent subjects who were classified as an extreme risk was diagnosed with new cavities on an initial follow up. However, this study failed to establish an association between initial enamel lesions at follow up and the risk of caries at baseline. Moreover, this study lacks information regarding the sensitivity and specificity of prediction, and that the researchers were unable to control confounding factors (Tellez et al., 2013).

A longitudinal study has been conducted by Gao et al., (2013) on preschool children to assess the validity of CAMBRA in its full and reduced forms. A total of 544, three-year-old pre-school children were enrolled. The result showed that the majority of children were at high-risk and only small proportions were at low and medium risk. The study concludes that reduced CAMBRA has high sensitivity and low specificity. On the other hand, full CAMBRA has unbalanced sensitivity and specificity Table 2.1. However, Gao et al., 2013 reported poor reliability of CAMBRA in this study Table 2.4.

The reasoning-based tools (CAT & CAMBRA) can be useful for educational activities for dental students to describe the factors which can cause caries. Both can be used in situations where the concern is to identify high-risk individuals only (Featherstone, 2004; Gao et al., 2013).

2.8.3 Risk factors identified by International Caries Management and Classification System (ICCMS)

The ICCMS has adopted the philosophy of CAMBRA caries risk assessment. In ICCMS, two factors are assessed namely caries risk factors at patient level and caries risk factors at intraoral level. The patient-level risk factors include head and neck radiation, dry mouth, inadequate oral hygiene, high frequency of sugar intake, lack of exposure to fluoride, high caries experience of mothers and caregivers, dental attendance and socioeconomic status. According to ICCMS, individuals with exposure to head and neck radiation will be automatically considered as high caries risk. The intraoral level caries risk factors include hypo-salivation, ulceration, exposed pulp, abscess, caries experience, thick plaque, appliances or restorations, bottle feeding and exposed roots. Individuals with hypo-salivation, ulceration, exposed pulp, and abscesses are considered as high caries risk.

ICCMS evaluates the likelihood of caries progression by stratifying the individual into low, medium and high caries risk, and current caries activity status at the patient levels. The caries activity is classified into three categories which are none, initial, moderate/extensive. The caries activity and risk levels are entered in the likelihood matrix that stratifies the individual according to their low, medium or high likelihood of developing new carious lesion or progression of the lesion. However, there are no studies available that have evaluated the ICCMS system so far.

2.8.4 National University of Singapore or NUS-CRA

The NUS-CRA was established using epidemiological data from pre-school children of Singapore. In this program, caries risk is also estimated by applying algorithms and reported as a percentage chance to avoid caries. As in Cariogram, the percentage of chance to avoid caries is also reported using five categories. NUS-CRA uses a total of 10- 11 risk factors for caries risk assessment which include age, ethnicity, socioeconomic status, infant feeding history, diet, fluoride, oral hygiene, past caries experience, systemic health, and counts of lactobacilli and streptococci Table 2.2. This system can also be used in both full and comprehensive form, just like Cariogram program. High sensitivity and specificity of the comprehensive (81% / 85%) and reduced (82% / 73%) version have been reported by Gao et al. (2013) when it was used on pre-school children of Singapore. However, the application of this system is yet to be tested on other populations. Moreover, Gao et al., (2013) fails provide the reliability of this tool Table 2.4.

2.8.5 Cariogram

The complicated nature of caries risk has led to the development of a computerised program for caries risk assessment knows as Cariogram, which is useful in evaluating caries risk (Tellez et al., 2013). The first electronic version was developed and launched by Professor Douglas Bratthall in 1997. Cariogram was designed to demonstrate the link between caries and associated factors, to clarify the chance to avoid caries, to produce a graphical presentation of caries risk, and to prescribe preventive treatments (Bratthall et al., 2004).

Cariogram is a graphical picture showing the individual's risk of developing new caries in the future. Also, it explains to what extent different variables impacts the risk of dental caries. However, it does not identify a specific number of cavities that will or will not occur in the future. It somewhat demonstrates an over-all risk situation. It can be utilised in clinics and for educational activities (Bratthall et al., 2004). Cariogram is both predictor and risk model because it can identify the risk levels and the risk factors to assist planning of intervention (Singh et al., 2018).

Cariogram considers various pathological and protective factors such as caries experience, systemic diseases, diet contents and frequency, amount of plaque, mutans streptococci, fluoride sources, saliva secretion, buffering capacity and professional clinical judgment. However, social factors such as socioeconomic status is not incorporated into the Cariogram because it has no direct effect on the tooth surface (Bratthall et al., 2004; Bratthall & Hansel, 2005). However, the factors caused by the poor socioeconomic status and directly linked with caries such as dietary intake; oral hygiene and access to fluoride are included in Cariogram for risk assessment.

Every factor in Cariogram can be scored from 0-3, where 0 stands for the best condition and 3 stands for the worst scenario. The graph of Cariogram shows five different sectors of different colours.

1) For diet, a combination of diet frequency and content (dark blue).

2) A chance to avoid dental decay classified in five categories (green).

0-20%, 21-41%, 41-60%, 61-80% and 81-100%

3) Bacteria and plaque (red).

4) Susceptibility is the combination of fluoride programmes and saliva buffering capacity (light blue).

5) Circumstances sum of past caries experience and related disease (Yellow).

Cariogram also includes two factors which are country and group area; both elements are divided further into three categories which are standard set, low risk and high risk. In the case of a country factor, the default setting (standard set) is for industrialised countries. The high and low risk can be chosen for a patient according to their requirement which will change the chances to avoid caries without affecting the relationship between other factors. In the case of a group factor, the standard set is an appropriate choice for the specific population group. The high and low risk can be chosen according to the group in mind (Bratthall et al., 2004).

The Cariogram estimate the caries risk by using a complicated formula containing many ‘if’ conditions. All factors have been given a specific weight according to the chosen score, and as the scores increase the weight of that factor will be higher. For example, in the default settings, the frequency of food intake factor has a higher weight than factors related to diet content. Similarly, the factor of bacterial counts has a higher weight as compared to the factor of plaque measurements. If two factors in the same group, such as diet content and frequency of food intake have high scores, additional weight to risk is given. It is also applicable for plaque amount and mutans streptococci counts. Addition weight is added to risk if several groups have high scores. In case of non-use of fluoride heavyweight to the risk will be added. Cariogram also considers the operator’s ‘clinical judgment’, and weights to the risk are added depending on the score selected for an individual (Petersson et al., 2002).

The weights associated with factors in Cariogram are created by the interpretation of data from numerous epidemiological, clinical studies and case reports from the literature in which various factors have been compared to caries incidence. The program contains about 5 million combinations of factors, and how the outcome for each combination can only be seen in the program (Petersson et al., 2002).

To achieve an appropriate risk assessment from Cariogram bacterial and saliva assessment is required. However, these assessments are not available to every dentist (Graham, 2009), and they are also expensive. Moreover, some studies have shown that reduced Cariogram can still be used without performing saliva and microbial testing in children (Gao et al., 2013; Dias et al., 2017). A study was conducted to assess the risk predictability of reduced and full Cariogram on 392 school going children of 10-11 years old for two years by Petersson et al., (2010b). The authors conclude that despite increased sensitivity and reduce specificity, reduced Cariogram can still identify low caries risk children.

Gao et al., (2013) conducted a longitudinal study on 544 pre-schoolers to assess the validity of caries risk assessment tools in full and reduced form of Cariogram, NUS-CRA and reasoning-based tools (CAT, CAMBRA). The results of the study showed that the Cariogram was able to identify two third of subjects with low risk. It was also reported that both the reduced and full Cariogram have almost balanced specificity and sensitivity, and the results were better when compared to reduced and full CAT and reduced and full CAMBRA Table 2.1. However, Gao et al., 2013 fails to report the reliability of Cariogram in this study Table 2.4.

Cabral et al., (2014) evaluated the ability of a form-based Cariogram to identify risk level of 150 school children aged 5-7 years and to assess the link between caries risk and factors in Cariogram. The results showed that 86% of children were at medium risk and only a few children categorised as high risk (8%). About 6% as low risk despite having high mean DMFT. The saliva and microbial testing were not conducted. The forward regression model was used to correlate the risk factors and caries risk. The results showed significant correlations between factors such as previous caries experience, oral hygiene, the frequency of sugar intake and fluoride resources. The results of a study showed that form-based Cariogram could be used to identify school children at low, medium and high caries risk.

The application of Cariogram is easy because it only requires 7-9 factors to establish the caries risk profile Table 2.2. On the other hand, 11 factors are required by NUS-CRA, 13 factors by CAT and 14 factors CAMBRA which makes the application of these tools more time consuming. The determination of risk level is quick and easy in Cariogram because it is done by algorithm and provides refine risk estimates as compared to reasoning-based tools which provides rough risk estimates.

So far, the reduced Cariogram with limited risk factors has been shown to effectively predict caries risk in both longitudinal studies and cross-sectional surveys (Campus et al., 2012; Lee et al., 2013; Hänsel et al., 2013; Sundell et al., 2015). In addition to that at present, good quality data is only available regarding the efficacy of Cariogram in predicting caries development as compared to other caries risk assessment models (Cagetti et al., 2018). In addition, to that balance sensitivity and specificity of reduced Cariogram was reported by Gao et al., 2013.

The available NUS-CRA data is regarding the application of this tool on pre-school children of Singapore and further studies on other age group from different population is required. On the other hand, CAMBRA and CAT can be used in situations where the concern is to identify high-risk individuals only because of their criteria of determining caries risk Table 2.3 (Featherstone, 2004; Gao et al., 2013).

Table 2.1: Sensitivity and specificity of algorithm and reasoning-based tool reported by Gao et al., 2013.

Risk assessment tool	Sensitivity %	Specificity %
Algorithm Based		
Reduced Cariogram	62.9	77.9
Cariogram	64.6	78.5
NUS-CRA	78.1	85.3
Reduced NUS-CRA	73.6	84.7
Reasoning Based		
CAT	98	6
Reduced CAT	98	6
Reduced CAMBRA	93.8	43.6
CAMBRA	83.7	62.9

Table 2.2: Factors in used for risk assessment by algorithm and reasoning-based tools.

Factor Comparison					
Factors	Reduce Cariogram	Cariogram	CAT	CAMBRA	NUS-CRA
Age					Yes
Ethnicity					Yes
Socioeconomic status			Yes	Yes	Yes
Infant feeding history					Yes
Dental attendance			Yes	Yes	
Oral hygiene	Yes	Yes			Yes
Past Caries	Yes	Yes	Yes	Yes	Yes
White spot lesion					
Dental appliances			Yes	Yes	
Microflora		Yes	Yes	Yes	Yes
Saliva Flow/ Buffer		Yes	Yes	Yes	
Diet	Yes	Yes	Yes	Yes	Yes
Fluoride Exposure	Yes	Yes	Yes	Yes	Yes
General Health Condition	Yes	Yes	Yes	Yes	Yes
Plaque	Yes	Yes	Yes	Yes	
Family experience			Yes	Yes	
Radiograph			Yes		
Clinical Judgement	Yes	Yes			
Bottle use				Yes	
Xylitol				Yes	
Enamel texture			Yes		
Total	7	9	13	13	10

Table 2.3: Procedure of determining caries risk level by caries risk assessment tools.

<table>
<tr><th></th><th>Reduced Cariogram</th><th>Cariogram</th><th>NUS-CRA</th><th>CAT</th><th>CAMBRA</th></tr>
<tr><td>Defining Low risk</td><td colspan="3" rowspan="2">Algorithm computer calculations</td><td colspan="2">Reasoning check list / Manual charting</td></tr>
<tr><td>Defining High risk</td><td colspan="2">Considered individual at high risk if belong to low socioeconomic status</td></tr>
</table>

Table 2 4: Reliability and validity of algorithm and reasoning based-tools (Christian et al., 2018).

Studies	Reliability	Measurement error	Content validity	Construct validity	Criterion validity	Responsiveness
			Cariogram			
Holgerson et al., 2009	N/A	N/A	Poor	Fair	Good	Good
Gao et al., 2010	N/A	N/A	Poor	Fair	Good	Good
Gao et al., 2013	N/A	N/A	Poor	Fair	Good	Good
			NUS-CRA			
Gao et al., 2010	N/A	N/A	Excellent	Fair	Good	Good
Gao et al., 2013	N/A	N/A	Excellent	Fair	Good	Good
			CAMBRA			
Gao et al., 2013	Poor	Poor	Poor	Fair	Good	Good
Chaffe et al., 2016	Poor	Poor	Excellent	Fair	Excellent	Excellent
			CAT			
Gao et al., 2013	Poor	Poor	Poor	Fair	Good	Good
Yoon et al., 2012	Poor	Poor	Poor	Fair	Good	Good

2.9 Diagnosis of dental caries

Diagnosis is a collection of information regarding the signs and symptoms of a disease that can be acquired by an intraoral examination, using additional diagnostic apparatus, information regarding disease history, risk factors and biological knowledge (Tikhonova, 2013). In dentistry, the primary objective of making a diagnosis is to choose the best intervention for individual receiving care to gain perfect long-term health outcomes (Nyvad et al., 2008; Tikhonova, 2013).

The diagnosis of dental caries is practised at two levels which are patient and tooth surface level (Ismail et al., 2013). At the tooth surface level, caries diagnosis is based on collecting information regarding signs and symptoms of caries by performing lesion recognition, measuring the severity and progression. On the other hand, at the patient level, caries diagnosis is achieved by collecting information regarding caries risk factors. By combining all information obtained from patient level diagnosis, dental hard tissue examination, tracking of lesion progress over time and patient preferences help in establishing a caries management plan (Pitts et al., 2011; Ismail et al., 2013).

The valid, reliable and accurate diagnostic system is necessary to obtain a good picture of disease distribution in a population before implementing measures to control it (Nyvad et al., 2008). However, the accuracy and reproducibility of available caries diagnostic methods are still questionable (Baelum et al., 2008). The possible explanation of this effect is the regression and progression of a lesion during caries process which may cause errors in disease measurement, in addition to that self-limited nature of caries process (Fejerskov, 1997). Currently, the presence or absence of caries is decided by a diagnostic cut-off point of caries measuring index by which the practitioner prescribes treatment (Selwitz et al., 2007).

The most widely used approached for caries examination is a visual and tactile examination, and bitewing radiograph (Nyvad et al., 2008). In the literature, low sensitivity and moderate to the high specificity of visual and tactile inspection have documented (Bader et al., 2001). A recent prospective study conducted by Melo et al., 2015 on 32 teeth in 28 patients, reported moderate sensitivity (75%) and specificity (75%) for visual examination and higher sensitivity (100%) and lower specificity (42.9%) for tactile examination. Recently, new methods to improve the visual and tactile diagnosis have been developed which includes laser fluorescence, electrical caries monitor, fibre optic transillumination and dental loupes (Neuhaus et al., 2009). Despite, the limitations of the visual-tactile approach, it is still the best option to distinguish the status and stage of a carious lesion before prescribing intervention (Tikhonova, 2013).

Secondly, the bitewing radiograph is commonly used as a supportive method to detect carious lesion missed at visual examination (Tikhonova, 2013). The purpose of using bitewing radiograph is to estimate the lesion depth and its progression (Mendes et al., 2012). The reported sensitivity and specificity of radiographs in the literature is 53%-66% and 83%-95% respectively. However, the bitewing radiographs used for caries diagnosis cannot accurately estimate the depth of lesion and lesion activity (Tikhonova, 2013, Kidd, 2011).

2.9.1 Caries Measurement Systems

Currently, different indices are available to measure dental caries at different levels such as the DMF index, ICDAS, significant caries index (SIC). All these indices measure caries from a different perspective. The oldest index which is still in use by researchers is the DMF index recommended by the WHO (World Health Organization, 2013) and it is still in use due to its ease of use, validity and reliability (Mehta, 2012). On the other hand, critiques have pointed out various shortcomings of this index which are

1. Lack of ability to identify the teeth at risk of caries.
2. Only measure cavities with dentinal involvement.
3. Not valid to measure root caries.
4. Not useful for treatment planning.
5. For the older age group, it is invalid because teeth can be missing due to reasons other than caries.
6. Evenly count missing teeth, untreated decayed and well-restored teeth.
7. Allocation of maximum M element of DMF can cause incorrect estimation of caries experience, and allocation of minimum M component can create a contrasting effect.
8. Avoid recording of caries attack when it is happening.
9. Reach the saturation point when every tooth is involved (Broadbent & Thomson, 2005; Hiremath, 2011).

The Significant Caries Index (SiC) was introduced by Brathall (2000) to identify individuals with the highest caries rates in a population under evaluation. The SiC works by identifying individuals according to their DMFT scores and the one third of the individuals with highest caries scores are selected. The mean DMFT score for these selected individuals is calculated that value form the SiC index (Bratthall, 2000).

It was designed to overcome the shortcomings of mean DMFT value by the correct estimation of the skewed distribution of dental caries in developed countries which can cause incorrect conclusion that caries is controlled in the total population (Mehta, 2012). The SiC index is an extension of the DMF index because it works on the same principles for evaluating dental caries and it has similar shortcoming as DMF index. However, this index has more use in populations with a low prevalence of dental decay and have skewed caries spread (Mehta, 2012).

With time, various visual/visual-tactile systems were designed to measure both non-cavitated and cavitated carious lesions. First of which was the D1-D3 scale (WHO, 1979) after D1-D3 criteria more advanced systems were developed such as Nyvad system and International caries detection and assessment system (ICDAS II) and its modifications (Tikhonova, 2013).

The earliest system designed to measure the non cavitated lesion was D1-D3 scale (WHO, 1979). The application of this scale required drying of tooth surface before examination (Fejerskov & Kidd, 2008). The coding used for D1-D3 scale is as follows:

Surface Sound: No evidence of treated or untreated clinical caries (slight staining allowed in an otherwise sound fissure).

D1. Initial Caries: No clinically detectable loss of substance. For pits and fissures, there may be significant staining, discolouration or rough spots in the enamel that do not catch the explorer, but the loss of substance cannot be positively diagnosed. For smooth surfaces, these may be white, opaque areas with loss of lustre.

D2. Enamel Caries: Demonstrable loss of tooth substance in pits or fissures, or on smooth surfaces, but no softened floor or wall or undermined enamel. The texture of the material within the cavity may be chalky or crumbly, but there is no evidence that cavitation has penetrated the dentin.

D3. Caries of Dentin: Detectable softened floor, undermined enamel or a softened wall, or the tooth has a temporary filling. On approximal surfaces, the explorer point must enter a lesion with certainty.

D4. Pulpal Involvement: Dental Cavities with probable pulpal involvement.

The Nyvad criterion is based on a concept of the activity assessment of a carious lesion. This system can measure activity status of a carious lesion by assessing the visual and tactile surface characteristics as well as it can differentiate between non-cavitated, micro-cavitated and cavitated lesions (Nyvad et al., 1999; Nyvad et al., 2003; Tikhonova, 2013). In this system, the activity of a carious lesion is measured by the presence of dental plaque, colour, lustre, location, and texture of the lesion. To assess the surface integrity and texture, sharp probe can be used to remove plaque (Dikmen, 2015). Like ICDAS II, Nyvad is also related to the contemporary evidence-based caries treatment approaches and provide support in selecting treatment approach by lesion activity and severity. Nyvad criteria can be used in research and clinical practice to assist clinicians in risk assessment, treatment selection and monitoring of a lesion over a time (Nyvad et al., 2003; Tikhonova, 2013). For Nyvad criteria, the acceptable inter-examiner reliability ranges from the kappa values of 0.58-0.94 and the intra-examiner reliability ranges from 0.74-0.95 (Nyvad et al., 1999; Braga et al., 2009a, Braga et al., 2010).

In 2001, International Caries Detection and Assessment System (ICDAS) was introduced by researchers (Ismail et al., 2007). ICDAS offer flexibility for practitioners and investigators to select the stage of dental caries and other characteristics required for their investigations. This system was designed on the knowledge obtained from the systemic reviews of caries assessment systems (Ismail, 2004). It was upgraded to make studies more helpful for assessments, reviews and to achieve evidence-based dentistry (Ismail et al., 2007). Initially, ICDAS I was developed which was focused on caries in the crown part of the tooth and not on root caries (Mehta, 2012). Later, ICDAS II (full

ICDAS) was introduced which is concentrated on caries in the crown part of tooth and caries with sealants and restorations (Banting et al., 2005) Table 2.5.

The variants of ICDAS are available which includes the full ICDAS or ICDAS II, modified ICDAS and ICDAS merged codes according to caries categories. All variants differ in terms of coding. The full ICDAS consist of 6 Codes which range from 0-6. The benefit of full ICDAS is that it can measure the lesion progression in the enamel and dentin and it is reliable in identifying dental caries even by the less skilled dental investigator. Full ICDAS is valid and reliable for clinical trials for measuring the effectiveness of preventive methods (Ismail et al., 2007; Pitts, 2009).

On the other hand, the modified ICDAS consist of 0 and A-6. The Code A is a merger of Code 1 and 2 of the full ICDAS. The modified ICDAS Codes from 3-6 are similar to the codes used in full ICDAS. In case of merged codes, the caries is categories into four stages which are sound surface (ICDAS Code 0), initial stage caries (ICDAS Code 1-2), moderate stage caries (ICDAS Code 3-4), and extensive stage caries (ICDAS Code 5-6). All variants can be applied to caries measurement (Braga et al., 2009a; De Amorim et al., 2011; Pitts et al., 2014). However, it can cause overestimation of caries experience (De Amorin et al., 2011).

The ICDAS has three types of codes 1) caries codes (Table 2.5, 2.6), 2) restoration codes (Table 2.7) and 3) special codes and considerations (Table 2.8, 2.9). ICDAS uses two digits scoring system to identify the restoration and caries. For example, if a tooth is filled with an amalgam restoration with localised enamel break down, a score of 4 will be given to the filling and a score of 3 to the cavity. Hence the two-digit Code for the tooth will be 43. ICDAS codes are designed to record both enamel and dentin caries. The tooth surface in ICDAS requires examination in a systematic way started from mesial surface followed by occlusal, distal, buccal and lingual. The full ICDAS is useful in epidemiological surveys involving children of age 5, 12, and 15 (lranzoCorte's &

AlmerichSilla, 2013). Recent evidence shows an equivalences between the WHO and full ICDAS indices on three parameters assessed which are DMFS, DMFT and overall caries prevalence at cut-off point 2, where ICDAS Codes 0 and A were considered as sound and Codes 3-6 were classified as caries (Braga et al., 2009a; lranzoCorte’s & AlmerichSilla, 2013). Studies conducted on preschool children have also shown that the cut-off point where ICDAS Codes 3-6 were considered as caries exhibits discriminant validity comparable to the WHO criteria (Braga et al., 2009a; Mendes et al., 2010).

A possible explanation for considering ICDAS Code 3-6 is the histological evidence which shows that at this stage caries may have advanced into the dentin. Therefore, it is concluded that this stage it can be compared to WHO criteria (Braga et al., 2009a; Braga et al., 2009b; lranzoCorte’s & AlmerichSilla, 2013). However, the only factor which can limit the use of ICDAS in surveys is a longer examination time (Braga et al., 2009a; lranzoCorte’s & AlmerichSilla, 2013).

The intraoral examination with full ICDAS requires drying of the tooth surface with compressed air. The need for compressed air has hindered the use of ICDAS in developing countries. In full ICDAS the compressed air is required to detect Code 1, 2 and 3. However, Code 1 and 2 is enamel lesion with little difference in the mineral loss and has the same preventive treatment which makes reporting of Code 1 in an epidemiological survey questionable. Similarly, the ball ended WHO probe can be used to identify Code 3 lesions. Therefore, in the case of an epidemiological survey, the simple approach is not to assess Code 1 (De Amorim et al., 2012).

Evidence shows that in field studies, drying can be done with cotton wool/gauzes (Pitts, 2009; Tomita et al., 2014). However, it requires the merging of Code 1 with Code 2 as Code A. This is termed as modified ICDAS (Table 2.6). The use of full ICDAS is only recommended if caries detection tools (Radiographs, Fiber Optic Transillumination) are available (Pitts, 2009).

The ICDAS system is best suited with the current caries management approach which relies on patient risk level, type of tooth surfaced affected, lesion severity (Ismail et al., 2013). The desired reliability of the ICDAS technique is evident when applied by well trained and calibrated examiner (Tikhonova, 2013). The acceptable inter-examiner reliability ranges from the kappa values of 0.62-0.91 and the intra-examiner reliability ranges from 0.59-0.88 (Ismail et al., 2007; Jabolonski et al., 2008; Braga et al., 2009a, Braga et al., 2010). The use of ICDAS II as a caries diagnostic method is suggested in a population with high caries risk (Mitropoulos et al., 2010). It is a widely used standardised system and allows international comparison of caries pattern (Tikhonova, 2013).

Both ICDAS II and Nyvad criteria can detect caries from its initial stage using visual and tactile signs and are the most advanced criteria's to use in research and clinical practice (Nyvad et a., 1999; Tikhonova, 2013). Also, both have demonstrated good reproducibility and validity in measuring carious lesion and their severity in vivo studies conducted on primary teeth. However, ICDAS II seemed to overestimate the caries activity assessment of cavitated lesion (Braga et al., 2010). Both criteria's differ in many ways such as Nyvad criteria used a single score to determine severity and activity, can be applied to the tooth surfaces covered with plaque, and a sharp probe is recommended for Nyvad criteria. On the other hand, ICDAS II criteria use separate scores, can only be applied to clean tooth surfaces, and the ball ended probe is recommended for ICDAS II criteria (Dikmen, 2015).

The purpose of developing different criteria for caries measurement is to minimise bias in caries measurement. However, there is no consensus regarding the gold standard measurement of caries, and caries detection methods are subject to errors with less than perfect reliability and validity (Gomez, 2015). A systematic review on various CRA models showed an inconclusive evidence of the effectiveness of standardised CRA models in assessing and predicting caries status. This may be because the included studies were very heterogeneous in terms of populations (Cagetti et al., 2018). Existing guidelines for caries management were developed based on populations with different caries and sociodemographic background. With caries being a lifestyle-based disease, it may not be suitable to directly extrapolate other guidelines recommendations to other populations of different settings (Usha, 2018). For the same reason, it is also not possible to have a gold standard for caries prediction model.

Table 2.5: Caries codes for Full ICDAS

Codes	Explanation
0	No evidence of caries
1	First visual change in enamel: opacity or discoloration is visible at the entrance of the pits or fissure seen after prolong drying.
2	Distinct visual change in enamel visible when wet, lesion must be visible when dry.
3	Localized enamel breakdown (without clinical visual signs of dentinal involvement)
4	Underlying dark shadow from dentin
5	Distinct cavity with visible dentin
6	Extensive distinct cavity with visible dentin

Table 2.6: Caries codes for modified ICDAS

Codes	Explanation
0	Sound
A	Distinct visual change in enamel
3	Localized enamel breakdown (without clinical visual signs of dentinal involvement)
4	Underlying dark shadow from dentin
5	Distinct cavity with visible dentin
6	Extensive distinct cavity with visible dentin

Table 2.7: Restoration codes for ICDAS.

Code	Explanation
0	Sound: i.e. surface not restored or sealed (use with the codes for primary caries)
1	Sealant, partial
2	Sealant, full
3	Tooth coloured restoration
4	Amalgam restoration
5	Stainless steel crown
6	Porcelain or gold or PFM or stainless steel (porcelain fused to metal crown) crown or veneer or inlay or onlay or other restorative material
7	Lost or broken restoration
8	Temporary restoration

Table 2.8: Special codes for ICDAS

Codes	Explanation
90	Implant for other non-carious related reasons
91	Implant placed due to caries
92	Pontic placed for reasons other than caries
93	Pontic placed for carious reasons
96	Tooth surface cannot be examined: surface excluded
97	Tooth missing because of caries (tooth surfaces will be coded 97)
98	Tooth missing for reasons other than caries (all tooth surfaces will be coded 98)
99	Un erupted (tooth surfaces coded 99)

Table 2 9: Special codes for ICDAS

Non-vital Teeth	Score the teeth for caries same as for vital teeth
Supernumerary Teeth	Examiner has to identify the legitimate teeth and scored that teeth
Primary and Permanent Teeth	If both primary and permanent teeth are present in a single space than only permanent teeth will be counted.
More than 1 Carious Lesion on a surface	The worst lesion should be scored, though scoring pits and fissures separately to free smooth surfaces is an option.
Partial Coverage Restoration	The surface must be scored separately
Crown of Tooth Destroyed by Caries	The tooth must be scored as D_6.

2.10 Additional diagnostic tools

In routine practice, bitewing radiographs are used as a supportive tool to increase dentist accuracy in measuring advanced carious lesion. The large demineralized zones allow filtration of x-rays showing radiolucent zone (Mendes et al., 2012; Hernandez et al., 2017). However, lack of demineralization in early carious lesion prevents detection through x-rays. Enamel carious lesion with a maximum of 40% mineral loss can be detected through radiographic assessment (Hernandez et al., 2017). However, due to the high film cost, lack of radiograph facilities and possible biological hazards, bitewing radiographs are sometimes not used in both clinical and research activities (Tikhonova, 2013), which could cause incorrect reporting of interproximal cavitated lesions. In the case of non-cavitated lesions, the more accurate way is visual inspection as compared to x-rays (Mitropoulos et al., 2010).

The use of LED (Light Emitting Diode) headlight illumination mounted on dental loupes can be used to improve visual assessment. This has been adopted in practice to improve accuracy by the dentists (Friedman, 2004; Ari et al., 2013). In clinical settings, various diagnostic aids are available to detect caries; however, in the field where conditions are compromised, appropriate diagnostic tools may not be available to assist in detecting dental caries. Few studies suggest that examination under low magnification aids can improve the diagnosis of dental caries (Ari et al., 2013; Kengadaran et al., 2017). Ari et al., (2013). showed that visual aids (low-powered magnification plus LED headlight illumination) could easily be used in daily clinical practice without affecting examiner reliability that may be due to the enhanced visibility of the occlusal surface. Similarly, Kengadaran et al., (2017) also reported that no significant difference was found between visual examination and examination conducted with low magnification with LED headlight. However, the specificity of vision was 97% under low magnification as compared to the visual examination with a specificity of 95%, indicating that examination with low magnification is a better confirmatory test.

2.11 Caries management

Two types of caries management approaches are in practice; the operative approach and contemporary approach. In the case of operative approach, clinicians diagnose caries only when the cavitation has occurred in a tooth. Dental restorations are placed to limit the progression and to rehabilitate tooth function (Tikhonova, 2013). The restoration approach has been shown to be very successful in managing dental caries (Qvist, 2008; Tikhonova, 2013). However, the lifespan of dental restorations is limited, and replacements are often required. This tooth death spiral phenomena consequently results in loss of additional tooth structure which exposed tooth to fracture, pulpal involvement, crown placement and extraction. All these events are very costly (Qvist, 2008; Tikhonova, 2013).

Moreover, tooth restoration is a risk indicator for new lesion development. Although the need for operative treatment cannot be overlooked, this approach cannot cure dental caries (Kidd, 2011; Tikhonova, 2013). However, this approach can be considered as an element of a more advanced caries treatment where the control of caries using non-invasive therapy is the main focus (Tikhonova, 2013).

The contemporary approach in caries management is one that focuses on risk-based patient-centred strategies. This approach aims to prevent the occurrence and advancement of initial enamel lesion via a preventive approach, without causing damage to tooth structure (Ismail et al., 2013). The current understanding of the dental caries process shows that the progression of a carious lesion can be controlled by creating equilibrium between tooth mineral and oral fluids by modifying caries risk and caries protective factors. For example, good access to fluoride and effective plaque control are found to be effective in caries control (Marinho et al., 2002, 2003a, 2003b, 2004; Kidd, 2011).

Similarly, the application of fissure sealant is also useful in treating initial carious lesion (Tikhonova, 2013). The contemporary treatment approach is recommended as the primary therapy for caries control and has long-term health and financial benefits (Tikhonova, 2013).

The use of this preventive approach is supported due to various reasons which are

1. Caries control at a microbial level can be achieved via methods at an individual level by modifying the risk factors and factors that initiate the caries process and its progression (Tikhonova, 2013). There is a need to categorise the levels of caries risk regularly throughout life because the risk indicator and predictors are different and can change with time for every individual (Ismail et al., 2013; Tikhonova, 2013).
2. The mechanism of dental caries disease process supports the use of non-invasive treatment. The caries process depends on the physiological equilibrium between oral fluids and tooth mineral. Modification or elimination of caries-causing factors can achieve this equilibrium and incorporating protective factors such as fluorides.
3. It is necessary to distinguish between active and inactive lesion because active carious lesion can progress rapidly in the absence of professional therapy as compared to the non-active lesion which requires only daily tooth brushing (Nyvad, 2004; Ismail et al., 2013; Tikhonova, 2013).
4. The change in the prevalence, distribution and rate of caries progression is another factor which favours the adoption of a preventive approach (Tikhonova, 2013). Since the progression of dental caries is reduced, clinicians have more time to manage a carious lesion by applying non-invasive therapy without causing tooth damage (Tikhonova, 2013).
5. The variation in clinical stages of dental caries and the difference between them is another factor which supports the use of non- invasive approach. The treatment method for each staged depends on the severity of the carious lesion. Thus, to prevent

progression on initial lesion with non-invasive therapy is more appropriate (Ismail et al., 2013; Tikhonova, 2013).

In conclusion, the understanding of caries disease pattern favours the risk-based patient-centred non-invasive caries management to prevent and treat lesion at their early stage.

2.12 Measurement of caries increment

Dental caries increment is the most widely used measure to calculate disease frequency in longitudinal studies (Slade & Caplan, 1999). Dental caries increment is defined as ‘‘the number of new carious lesions occurring on tooth surfaces in a person during a specific period’’ (Slade & Caplan, 1999). The primary aspect of dental caries increment is that it can summarise the different events which are happening within the participants over a period and reported in a single outcome measure.

For measuring dental caries increment, different approaches are available such as DMF increment, crude caries increment (CCI), net caries increment (NCI) and adjusted caries increment (ADJCI). However, each method has its limitations and advantages (Broadbent & Thomspon, 2005). The DMF increment is estimated by subtracting the DMFT/DMFS score at baseline from their corresponding DMFT/DMFS score at next follow-up. This method is quick and easy to perform. However, this method does not allow adjustments for reversals.

The second method describes by Beck and coworker is crude caries increment. It is measured at the tooth surface level by comparing data from two events. Although this method is more accurate as compared to DMF increment, it is difficult, time-consuming and does not allow for reversal adjustment (Beck et al., 1995).

In the majority of longitudinal studies, the caries increment is estimated using net caries increment. The estimation of net caries increment is similar to the crude caries increment, and it allows for reversal adjustment. It is estimated at an individual level by subtracting reversals from the positive increments (Broadbent & Thompson, 2005).

Beck and colleagues proposed a caries estimation method known as adjusted caries increment (Beck et al., 1995). Adjusted caries increment (ADJCI) is a method to correct examiner reversals; however, it works on the assumption that examiner reversals are more common than actual reversals. This method is applicable if the percentage of reversals is more than 10% of the number of surfaces with decay at initial examination (Broadbent and Thompson, 2005). The methods mentioned above can calculate increment only when the threshold of decay is cavitation. However, when the threshold for decay is non-cavitation, two methods can be used transition scoring system (TSS) and modified Beck's method or ADJCI (Ismail et al., 2011).

Transition scoring system is developed to compute caries incidence over time. This method requires a transition matrix to examine potential transitions and transition specific weight to describe incidence at surface level. This system allows adjustment for biologically plausible and biologically implausible reversals.

Modified Becks method is a modified version of ADJCI proposed by Beck et al. (1995). Ismail et al., (2011) modified this formula to incorporate non-cavitated and cavitated lesion. This method allows adjustment for reversal but cannot differentiate between biologically plausible and biologically implausible reversals. In this method, counts of surfaces with progression, regression and no progression nor regression are applied to the formula and child level increment can be estimated. This method is based on three events progression, no progression nor regression and regression for caries estimation.

A 4-year longitudinal cohort study focusing on the oral health of 638 low-income African-American children of age 0-5 was conducted to compare both TSS and ADJCI by Ismail et al., (2011). The study includes primary tooth surface data collected on two different points in time. In this study, caries increment was calculated at two levels, a combine non-cavitated plus cavitated level and cavitated level only. The result showed that both systems find agreement in mean increment scores when estimated at cavitation level. On the other hand, when increment was calculated using both methods at the non-cavitated+cavitated level, TSS shows slightly higher mean increment score as compared to ADJCI due to which authors concluded that TSS is somewhat superior. However, Ismail et al. suggested that this effect can be due to the difference in weighting schemes for transition in both systems. The TSS has case specific weights for all transition including the non-cavitated lesion. On the other hand, the Modified Beck method has used only three transitions which are progression, no progression nor regression and regression. In conclusion, both methods can be used and equivalent in computing caries increment (Ismail et al., 2011).

2.13 Principles for analysing and reporting caries increment in longitudinal studies

Several issues can arise when computing caries increments in longitudinal studies which include defining units of observation, examiner misclassification (reversals), teeth lost due to caries, findings from more than two examinations, and multiple events such as caries initiation and progression (Slade & Caplan, 1999). For clinical examination of caries, it is essential to develop a mutually exclusive classification for the status of each observed unit, e.g., tooth surface (Slade & Caplan, 1999).

A widely adopted approach in studies that enumerate multiple events is to compute separate outcome measures (Slade & Caplan, 1999). In a study with three or more follow-ups, two or more than two events may occur, for example, a surface that changes from sound to fill to recurrent decay, or one event for initiation (e.g., sound to pre-cavitated) and another event for progression (e.g., pre-cavitated to cavitated). In this study, events recorded were no progression no regression, progression, and regression.

There are different strategies to overcome the limitation of missing teeth. One technique is to give the same score which was given at a previous examination before tooth extraction (Broadbent &Thompson, 2005). This method is applicable when the study has a short recall interval period (Slade & Caplan, 1999; Broadbent &Thompson, 2005). In the case of longitudinal study, a second option is to allocate the value of 0 to teeth extracted due to caries (Broadbent & Thompson, 2005).

Errors in investigators classification can result in recording caries initiation when in reality, none occurred (false increment) or caries reversal when in reality none occurred (false decrement). The positive association between high caries prevalence and examiner reversals is reported which shows that when the caries prevalence is higher, the numbers of examiner reversals is also higher as compared to the true reversals. In addition to that examiner also tends to make more error in caries diagnosis in subjects with known risk factors for future caries experience (Beck et al., 1995). The study design, examiner training, and quality control can help in minimising the misclassification (Bell & Klein, 1984). In this study, to reduce examiner misclassification and improve the quality of examination, examiner calibration, examiner blinding, and dental loupes were used. Moreover, in this study, 0 was assigned to the transitions associated with missing teeth due to caries to prevent overestimation of increment.

2.14 Management of Missing Data

In longitudinal studies, pre-set quantities of repeated measurements for all subjects are usually conducted at the same points in time at similar intervals. This design is known as balanced over time (Fitzmaurice, & Ravichandran, 2008). In longitudinal studies, it is important to control the level of dropouts. However, it is practically difficult to achieve. The potential of missing data to undermine the validity of results has been discussed in the medical literature (Sterne et al., 2009). Dropouts in longitudinal studies can reduce external validity, which affects the generalizability of the study findings to the total population. It can also reduce the internal validity of an investigation by affecting the correlation between factors in a study (Mason, 1999; Miller & Hollist, 2007).

Before addressing the problem of missing data, it is necessary to consider three aspects which are the proportion of missing data, mechanism of missing data and the pattern of missing data. The proportion of missing data is associated with the quality of statistical inferences. However, there is no prescribed limit for the acceptable percentage of missing data in a data set for statistical inferences (Dong & Peng, 2013).

There are three different mechanisms under which missing data is possible: randomly missing data (MAR), non-randomly missing data (MNAR) and data missing completely at random (MCAR). In the case of MAR, the assumption is that missing values depends on observed values only (Buhi et al., 2008). In the case of MCAR, missing values are not related to the observed and unobserved data. For example, individuals who do not appear at follow up due to the reason not associated with a study such as bad weather, an illness, or death in a family, and loss of some data due to a computer error. In the case of non-randomly missing data (MNAR), missing data is related to the values which are missing themselves. For example, individuals who prefer to use cocaine over the specified period and do not appear for a urine test would be expected to have the raised level of cocaine metabolites.

Consequently, missing data will be related to the unobserved cocaine level (Buhi et al., 2008). The non-randomly missing data are more complicated and cannot be ignored. On the other hand, MCAR and MAR are ignorable data and researchers can disregard the reasons and apply missing data techniques. The completely random and randomly missing data are possible in this study (Buhi et al., 2008).

The last aspect to consider is the pattern of missing data which can be univariate, monotone and arbitrary. The univariate pattern of missing data occurs if the same individual has missing data on one or more variables. Missing data is considered as monotone when the participant is dropout on any occasion; subsequently, the missing data occur on subsequent follow-up (Dong & Peng, 2013). The monotone pattern of missing data commonly occurs in longitudinal studies. The monotone missing data sub assumes the univariate pattern of missing data and both are easy to handle. The randomly missing data in any variable is considered as an arbitrary pattern of missing data (Dong & Peng, 2013).

There are several methods of handling missing data which includes deletion (complete case analysis), mean substitution and imputation techniques. These methods are common, easy to apply without any statistical expertise. The deletion technique depends on excluding the cases contain missing data. The drawbacks of this method are the loss of statistical power, loss of sample size and the reduce ability to estimate statistically significant results (Buhi et al., 2008). The second most widely used technique is mean substitution depends on replacing missing values with the mean score. This method prevents the reduction of sample size, and it is easy to use. However, the replacing of missing value with a single value in this technique affects the distribution of the variable by diminishing the variance that is naturally present (Buhi et al., 2008).

In longitudinal studies, to handle missing data, multiple imputation techniques are usually applied. Multiple imputation is a strategy to handle missing data it is used to substitute a missing value with a set of plausible values which have similar natural variability and uncertainty of the real value. The objective of applying multiple imputations is to permit variability regarding several distinct credible imputed datasets and merging results from the different data set (Sterne et al., 2009; Kang, 2013). The application of this method starts by forecasting of missing values using the available data from other variables. The missing values are replaced using repeatability with the predicted values. After performing imputation, multiple data sets are analysed by applying conventional statistical analysis and produce various results (Sterne et al., 2009; Kang, 2013).

The proportion of missing data in a study on the use of dental sealants on children conducted by the Mejia et al., (2011) was 53%-56%. Multiple imputation technique was applied by the authors to overcome the limitation of missing data. Initially, 10 imputations were carried out using sequential regression multivariate imputation technique which provided a final imputed data set for statistical analysis.

Another study that used multiple imputation technique was by Chaffee et al (2014) who evaluated the association between long duration of breastfeeding and dental caries. The proportion of dropout in this study was high due to the changes of address and contact information of the participants. In that study, multiple imputation was applied to replace missing values.

The strength of multiple imputations is a correction of variance problem caused by the mean substitution technique. In addition to that, this method allows examining the variation that occurs due to the imputation process and estimates statistical significance correctly. However, this method requires more statistical expertise and effort to create imputation and results (Buhi et al., 2008; Dong & Peng, 2013).

There is not a single missing data approach for every missing data situation. It is essential to understand the mechanism of missing data because different techniques have different assumptions about the missing data. For example, mean substitution and deletion methods assume that the mechanism of missing data is MCAR. Multiple imputations and other sophisticated method assume MAR and MNAR data (Buhi et al., 2008).

2.15 Pakistan-Country profile

The Islamic Republic of Pakistan is located in South Asia. Pakistan consists of four provinces and four federal territories (Buzan, 2004). The national capital of Pakistan is Islamabad. The landmass of Pakistan is 770.880 km2. Pakistan is a middle-income level country with a GDP (Gross Domestic Product) of $ 246.9 billion (The World Bank, 2014; Pakistan Welfare Department, 2015).

Pakistan is one of the most populous nations in the world with a population of about 188 million. The total male population is 51%. The life expectancy for males in Pakistan is 66 years and for females is 67 years (The World Bank, 2014). A total of 64% of the population resides in rural areas. The metropolitan city is Karachi which is situated in Sindh province. The total population of Karachi is 23.5 million. The entire area of Karachi is 3,527 km^2 (Official Web Portal of Karachi Metropolitan City, 2012).

The literacy rate in Pakistan is 57%. Literacy rate in the urban area is 75%, which is higher than the rural area at 49%. In Pakistan, primary education (Grade 1-5) starts at the age of 5 years and children remain in primary school up to the age of 9 years. The secondary education is divided into three parts, middle school (grade 6-8) for 10 to 12 years old, secondary education (grade 9-10) for 13-14 years old and higher secondary (grade 11-12) for 15-16 years old (International Bureau of Education, 2011).

2.15.1 Oral health care system in Pakistan

In Pakistan, the Pakistan Medical and Dental Council (PMDC) control the medical and dental profession. At the national level, planning for health is controlled by the Federal Ministry of Health. At the provincial level, the Department of Health control policies and provide services in government health sectors. Health care system in Pakistan is a mixture of the public and private healthcare system (Hameed, 2008; Ather & Sherin, 2014).

In Pakistan, the total number of general dental practitioners is 14,627 out of which 8500 is actively working (Pakistan Medical and Dental Council, 2015). The population to dentist ratio in urban areas is 1:20,000-49,999 and 1:200,000 people at best in rural areas (Beaglehole et al., 2009). In the case of dental auxiliaries, there are more than 2500 chairside assistants, 350 hygienists, 800 lab technicians, and 40, 000 unqualified denturists (Government of Pakistan, 2003).

The Governments spends 0.4% (50 billion PKR) of its GDP on health services (Kumar & Bano, 2017). The public sector covers 23% of health cost, and the remaining 77% is out of pocket payments to the private sector. In 2012-13, government spending was 79.46 billion rupees (0.35% of total GDP) on health care which was 44% higher compared to the expenditure in 2011-12. Government spending is more focused on preventive, curative services and infrastructure of health (Harchandani, 2012; Ather & Sherin, 2014). Neighbouring countries are spending more of their annual budget on health compared to Pakistan such as Afghanistan spends 8.1% of GDP, China spends 5.6% of GDP, Iran spends 6.7% of GDP, and India spends 4.0 % GDP on health (World Health Organization, 2015).

The Employees Social Security organisation covers only one million population and government departments such as Pakistan International Airline, Pakistan Railway, Water and Power Development Authority, Pakistan Telecommunication Limited and

Fauji Foundation provides medical cover to 0.93 million people. The armed forces also provide medical coverage to their employees. Private health insurance has no significant contribution. In 2010, the government started a pilot project of health insurance scheme which covers Benazir Income Support Program (BISP) recipients and provides up to 25,000 rupees per family per year as hospitalisation fees (The Network of Consumer Protection, 2005; Settle 2010).

Health care structure is shown in Figure 2.3. The health care structure is distributed according to the population distribution. For example, for every 5,000–10,000 people, there is one basic health unit (BHU) and rural health centre (RHC) for a population of 40,000–100,000 people. In total there are 1167 government hospitals, 5695 dispensaries, 5464 basic health units and 675 rural health centres (Gallup Pakistan, 2016).

The private health sector in Pakistan consists of for-profit providers, non-profit, non-governmental organisation (NGO), and an informal sector. The private sector provides the bulk of outpatient care. The health workforce in the private sector consists of doctors, dentists, nurses, paramedics, laboratory technicians, pharmacists, drug sellers, traditional healers and unqualified practitioners. Health facilities in the private sector are eight tertiary care hospitals, 692 medium-size hospitals and 73,650 private healthcare institutions. The private health services are more distributed in urban areas compared to rural areas. In Pakistan, the majority, 67.4% of people in Pakistan prefer to consult private healthcare service for health problems (Ather & Sherin, 2014).

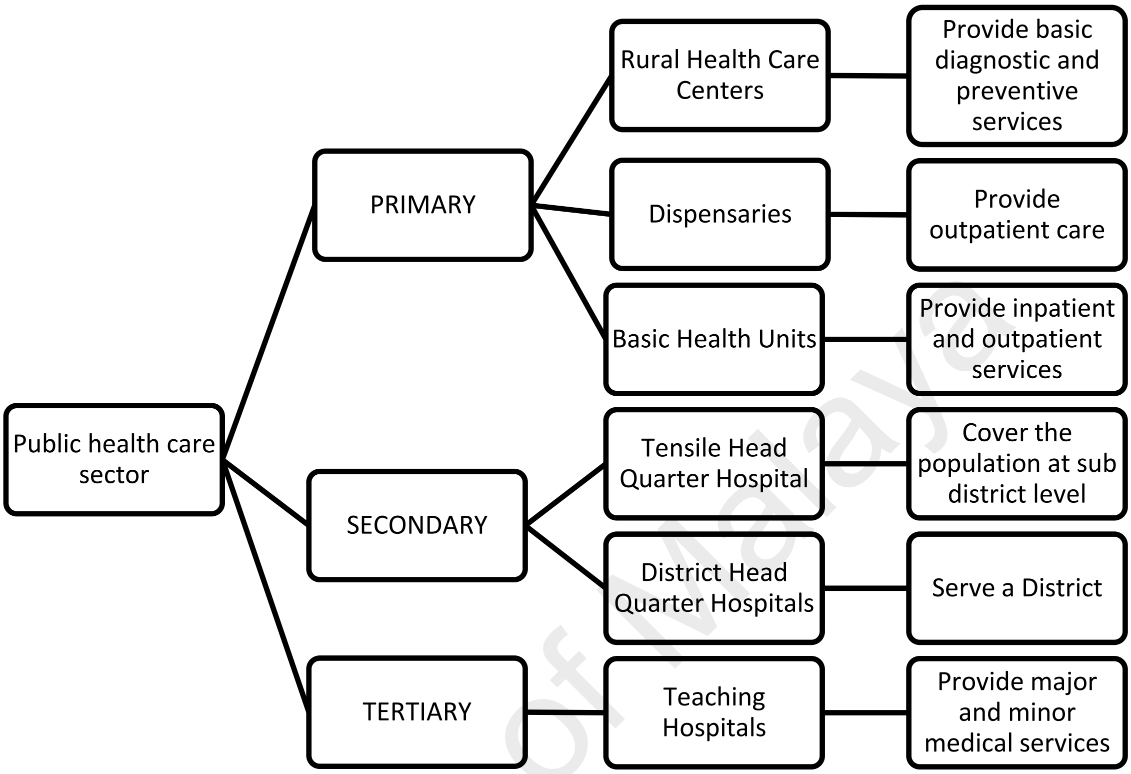


Figure 2.3: Public health care structure in Pakistan (Adopted from Shah et al., 2011).

2.15.2 Oral health delivery system

In Pakistan, oral health services are delivered by the Ministry of Health via dental facilities in different government administered hospitals, Rural Health unit and Basic Health unit (Figure 2.3). The health care delivery system is shown in (Figure 2.4). There is no budget allocation for oral health care services because most of the distributions are towards the control of communicable disease with a high death rate (Government of Pakistan, 2003). The primary dental cover in the public health system is delivered via rural health centres (RHC), dispensaries and basic health units (BHU). The health care services provided in primary health care facilities are extraction, restorations, scaling and prosthesis. There are no outreach oral health programs initiated by the Ministry of Health for population residing in interior areas of Pakistan. There are no preschool and school dental service programs offered by the Ministry of Health (Government of Pakistan, 2003).

At the federal and provincial hospitals specialist oral health services like oral surgery, orthodontics, operative, prosthetic dentistry, periodontology are provided. The public and private health sectors have a poor referral system from primary to specialist centres (Siddiqi et al., 2001). In the case of community oral health services, there are no programs of school-based fissure sealant application or fluoride varnish application offered by the Ministry of Health. Since 1952, school health programmes are a component of government health services, but in reality, it is not available on the ground. Also, the provincial government of Sindh, Pakistan, stopped its school health programs in 2006 because they were not achieving their objectives (Ahmed & Danish, 2013). School oral health promotion activities are usually arranged by the private and government dental institutes, mostly in urban areas but not on a regular basis (Haleem, 2006). Moreover, in urban areas, these activities are more focused on a few privileged schools (Dawani et al., 2012a).

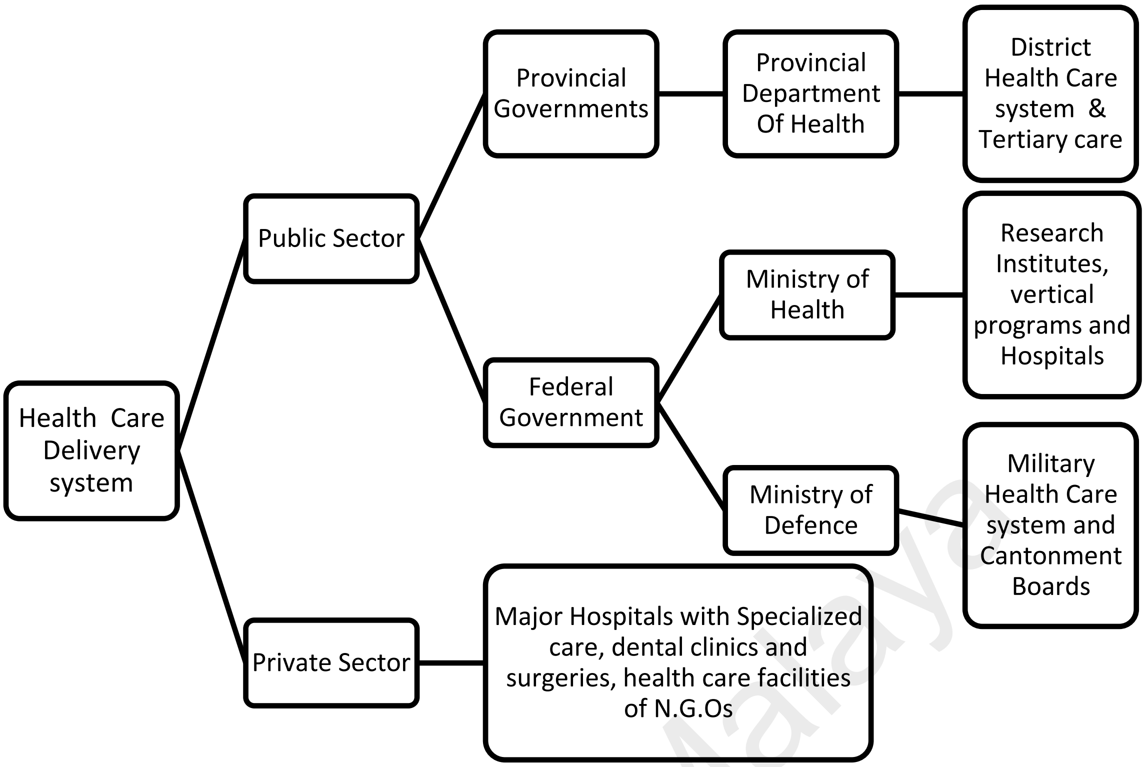


Figure 2.6: Oral health care delivery system

Figure 3.1: Bhakkar MapFigure 2.7: Oral health care delivery system

2.15.3 Overall situation of the healthcare system

There is no national public oral health policy available in Pakistan. Oral health was neglected when primary health care was first established in Pakistan resulting in significant gaps in the distribution of oral health care services. Reliable data regarding the actual need for oral health is insufficient. The most recent document on oral health, "Oral Health in Pakistan, a Situation Analysis" was published in 2003. Data regarding expenditure on oral health is not available (Harchandani, 2012).

The people of Pakistan are not satisfied with their current healthcare system (Government of Pakistan, 2003). The working hours of public health centres are insufficient. Health facilities lack the necessary resources, staff, drugs and equipment (Kurji et al., 2016). Only 0.6% of hospital beds per 1000 people are available in the public health system. Public health facilities lack funding, staff and charge out of pocket payments for apparently free services. Due to these factors, the utilisation of public health facilities is reduced, and patients prefer the treatment at private health facilities. (Hameed, 2008).

In rural health centres, 341 posts remain unfilled resulting in only one dentist is available for 0.5 million people. Also, there are a few rural health centres in the country where the dental surgeon has been posted but with no equipment availability. Furthermore, most of the public health centres lack dental material. Nearly 40% of the dental equipment is redundant. Moreover, dental materials and drugs are not incorporated in the essential drug list of rural centres (Shah et al., 2011). Many residential districts in Pakistan lack even the most critical emergency dental services. Also, the family program activities do not include oral health promotion. Only a small proportion of health budget is given out for the oral health programs (Government of Pakistan, 2003).

Like other developing countries oral health care services in Pakistan are more focused on treatment and are unable to treat rapidly spreading dental disorders such as caries (Government of Pakistan, 2003; Zhu, 2005; Beaglehole et al., 2009). The 90% of treatment provided in public dental clinics is extraction. Moreover, the concept of visiting dental clinics in Pakistan is not prevalent. People visit the dental clinic only when they have dental discomfort (Shah et al., 2011). Lack of knowledge and absence of symptoms (pain) is responsible for the delay in seeking dental treatment (Shah et al., 2011).

2.15.4 Fluoride levels in Pakistan

Fluoridation is known as the upward adjustment of water fluoride to a level where it can protect from caries without causing fluorosis (Mumtaz, 2007). The evidence has shown that fluoride can effectively reduce dental caries if combined with low sugar intake but unable to completely stop lesion development (Robert, 1995; Beighton et al., 1996). The optimum fluoride level required in drinking water to reduce caries progression is 0.7–1.2 ppm (Mumtaz, 2007). However, these levels are not suitable for every part of the world, especially for the tropical and sub-tropical regions of Asia and Africa. The optimum fluoride level is contingent on the level of caries, fluorosis, climate, dietary fluoride intake and fluid intake (Khan et al., 2004a).

Khan et al., (2004a) evaluated the water supply of 19 major cities of Pakistan. The analysis shows that in 13 cities of Pakistan the fluoride level is below 0.35 ppm; 0.4 ppm - 0.7 ppm in four cities; and the remaining two cities had water fluoride levels 0.9 ppm and 1.2 ppm respectively. Siddique et al., (2006) also reported that fluoride levels in water samples gathered from the subsurface, and river sources are below the suggested fluoride value. However, subsurface water in industrial areas has more than suggested levels of fluoride (>1.2 ppm) (Siddique et al., 2006).

Based on the annual mean maximum temperature of Pakistan of 29-degree centigrade, the recommended fluoride level for Pakistan is 0.35 ppm (Khan et al., 2004a). However, most of the water supplies in Pakistan had fluoride levels less than 0.35 ppm

(Khan et al., 2004a; Khan et al., 2002). Pakistan lacks the resources that are required to execute water fluoridation. Moreover, only 20% of the population has access to piped water supply, and the remaining is using natural water resources (Khan et al., 2004a). Hence, there is a need for alternate fluoride resources. The current evidence shows that wide variation exists in fluoride concentration in kinds of toothpaste marketed in Pakistan. They range from 10 ppm to 1647 ppm in imported brands and 426 ppm to 1444 ppm in local brands (Rafique et al., 2017).

2.15.5 Diet of Pakistani children

Diet can impact on oral health in several ways. It can influence the craniofacial development, affect oral mucosa, and can cause dental decay and loss of periodontal attachment (Moynihan, 2005). Evidence has shown that relationship exists between the intake of dietary sugar and caries occurrence (Szpunar et al., 1995; Rodrigues & Sheiham, 2000).

No national data exist regarding dietary patterns of the Pakistani population. Moreover, only a few studies have been conducted regarding the nutritional habits of the Pakistani population (Hyderi et al. 2010; Yakub et al., 2010). A cross-sectional study on private school children (n=362) was conducted in 3 Pakistani cities Karachi, Quetta and Lahore (Aziz et al., 2010). The objective was to match dietary outline and body mass index of prosperous school children and adolescents. Results showed that sweet, bakery items and fast food consumption is higher in children of Karachi (28.2%) as compared to Quetta (18.3%) and Lahore (24.1%). Moreover, the starch consumption in Quetta was higher (32.6%) compared to other cities.

A prospective descriptive study was conducted in Islamabad to assess the relationship between food habits and dental caries in 543 of 6-9 years old Pakistani children. The results showed that 56% of children ate chocolate and candies every day, 39.4% of children reported eating bakery product, 66% of children consumed sugar-sweetened tea, bread intake was reported by 84%, and 40 % brings high sucrose lunch to school. It was observed that the prevalence of dental caries was higher in the age group of 8 and 9 years old. Children who preferred daily candies intake had statistically ($p<0.05$) more decayed teeth. Moreover, high frequency of dental decay was reported in subjects who prefer intake of bread at breakfast with sweetened tea (Abdullah et al., 2008).

Iftikhar et al., (2012) conducted a cross-sectional study in private institutions of Karachi to evaluate the frequency of caries in children (n = 245) consuming snacks. The data showed that 53% of subjects consumed biscuits, 56% consumed sweets, 86 % ate ice cream, and 76 % consumed fries. The results showed that dental decay was 3.89 times more frequent in subjects consuming biscuits compared to those who do not. Similarly, caries was 4.28 times more frequent in children who ate fries compared to those who do not consume.

2.15.6 Dental caries in Pakistan

A national pathfinder survey reports that the prevalence of dental caries in 12-year-old Pakistani children is 50% (Government of Pakistan, 2003). This pathfinder survey was conducted in 21 districts of Pakistan. For each cluster, 25 -50 number of subjects from each index age groups were selected.

In large cities, two clusters of each index age group and one cluster of each index age group was selected in towns and villages. The total sample size of 400 for each city and 200 sample size for each town and villages were selected. The data of total 9246 subjects of index age groups were collected, and data of 500 subjects were not reported due to anomalies in entry (Government of Pakistan, 2003).

Although the frequency of caries among 12-year-old children in Pakistan was considerably high, their caries experience had improved from 2.1 in 1979 to 1.38 in 2003 (Government of Pakistan, 2003; WHO Oral Health Programme, 2000). Several isolated studies have reported the prevalence of dental caries among school going children in different regions of Pakistan for example:

1. A cross-sectional study was conducted in a rural area of Larkana in Pakistan to assess the frequency of dental caries among 600 subjects of age 13-20 and 21-30-year-old. This study found that the prevalence of dental caries in 13-20-year-old was 62% with a mean DMFT of 3.4 (Shaikh et al., 2014).
2. A study of 3-5-year-old children in Clifton region of Karachi reported a caries prevalence of 29% with a mean dmft of 1.1 (Charani et al., 2011). This low prevalence is because Clifton belongs to the higher socioeconomic status. However, a study on a similar age group (3-5-year-old) children conducted in the Saddar area of Karachi shows a 51% prevalence of dental caries (Dawani et al., 2012b).
3. A cross-sectional study of 399 school children of age 12-15 years in the peri-urban area of Karachi was undertaken to evaluate the dental caries status. The prevalence of dental caries was 66%. The mean DMFT value was 1.14 in 12 years old, 1.29 in 13 years old and 1.3 and 1.25 in 14 and 15-years old children respectively. The mean DMFT was higher in females compared to males. This study also reports the increase in DMFT score with the increase in age (Leghari et al., 2012).
4. A study, conducted among school children of 5-14 years old in the city of Lahore showed a prevalence of 71% (Ali et al., 2012). The results showed that mean decayed (d) and filled teeth (f) score of 5-11 age groups was 2.9 and the DMFT score of 12-14 years old was 3.7.
5. A cross-sectional study was conducted in Bhawal Victoria hospital in the city of Bahawalpur Pakistan on subjects of aged 11-70 years old. The prevalence of caries was 97%. Results showed that the mean DMFT score of 11-13 years old was 14±1.22 with increasing score in the older age group (Badar et al., 2012).

6. A cross sectional study conducted in public and private schools of Karachi on subjects of 6 and 12 years of age. The prevalence of dental caries among 12-year-old children was 40% with a mean DMFT score of 0.97±1.72 (Mohiuddin et al., 2015).

7. A cross-sectional study was conducted in randomly selected four public schools of Sargodha district of Pakistan. The schools were selected using the balloting method and were stratified according to the gender selected. Children of age 3-12 years old were selected. The mean scores DMFT score among 9-12 years old was 0.3±0.68 (Umer et al., 2016).

The mean scores reported in the above-mentioned isolated studies and a national epidemiological survey shows that the mean DMFT scores are low among 12-year-old children. The low mean DMFT scores in Pakistani 12-year-old children supports the rationale of our study as evidences suggest that caries progression is slower in a population with low mean DMFT scores. The six months recall may not be appropriate for caries management among 11-12- year-old Pakistani children.

2.15.7 Summary of literature review

Dental recall interval period for the management of dental caries must be planned according to the risk level of an individual. There are different types of recall visits reported in the literature. However, in conditions where resources are scarce and disease prevalence is high, the best approach is to plan management according to the risk levels. This approach has been adopted to treat dental caries because of its multi-factorial nature, disease progression and variation in its clinical stages.

Every individual has variation in exposure to caries causing factors which define their caries risk levels. It is necessary to identify the caries risk level of an individual and to identify each stage of dental caries accurately. For both activities, different types of tools such as Cariogram for risk assessment and International Caries Detection and Assessment System (ICDAS) of which published data regarding the validity, reliability and accuracy of these tools are available.

In Pakistan, unfortunately, minimal health budget is allocated to oral health services, the prevalence of dental caries in 11-12-year children is 50 per cent, sugars intake is frequent in children, and fluoride levels are less than 0.35 ppm. In addition to that, the majority of treatment provided for dental caries is based on invasive operative procedures, and dental practitioners still prescribe traditional six-months recall. Thus, there is a need to change current treatment practices and to adopt the risk-adjusted patient-centred strategies.

CHAPTER 3: METHODOLOGY

3.1 Research design

A prospective longitudinal study of 18 months duration was conducted from May 2016 to October 2017 in seven schools (two private and five public) of the Bhakkar city of Punjab, Pakistan (Figure 3.1). This study consists of baseline and follow-up examinations at six months interval up to 18 months. The population of Bhakkar city is 300,000 (Tehsil Municipal Administration Bhakkar, 2007). This area was selected for the study because dental caries status among the school children population of the Bhakkar city has never been documented.

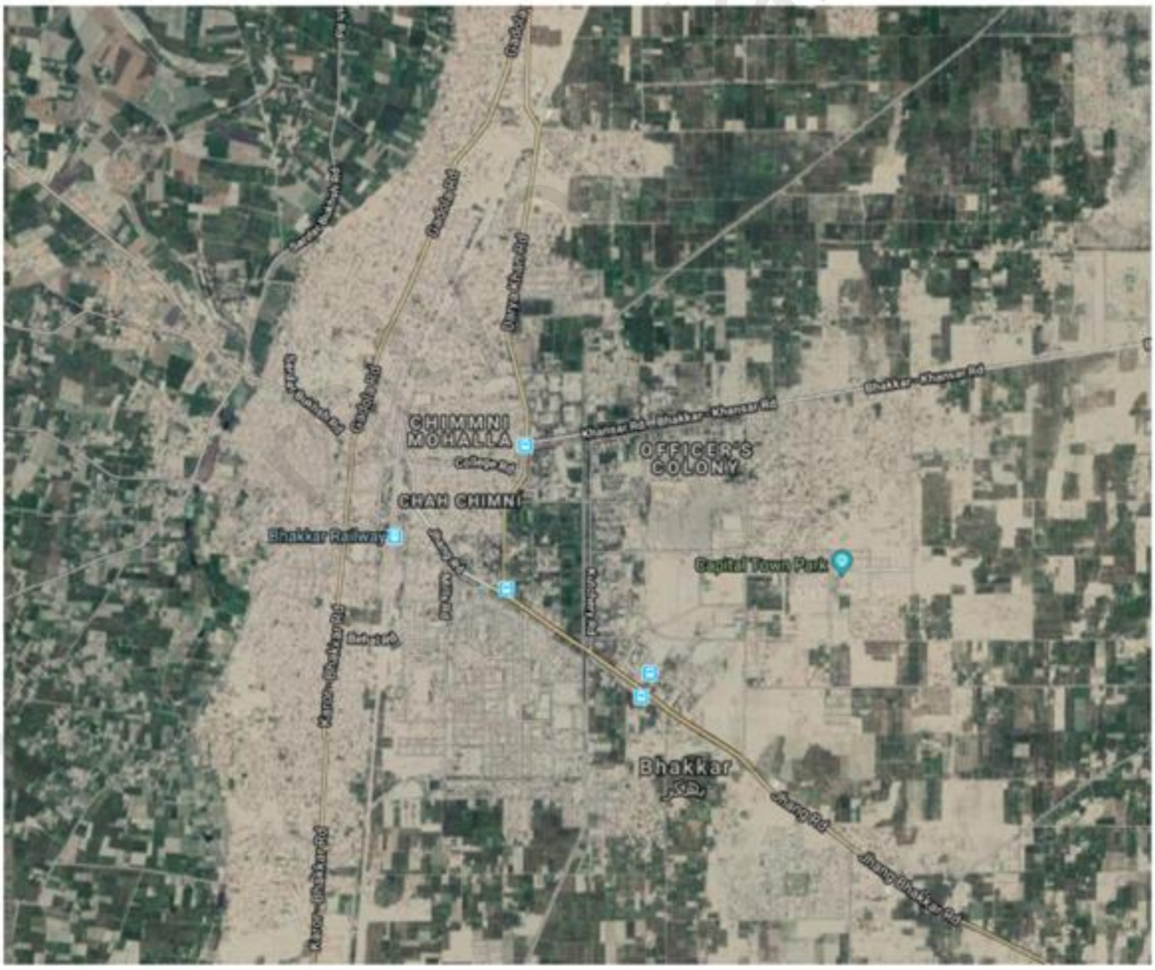


Figure 3.2: Bhakkar Map

Figure 3.3: Bhakkar Map

3.1.1 Sample Size Estimation

The sample size for this study was computed by calculating the number required for all the study objectives. The most notable sample size obtained out of all estimates was taken as the final sample size that would support all study objectives (Naing et al., 2006). The sample size estimation for objective 4 gives the most significant number of samples required. The sample size was calculated based on the mean caries progression rates obtained from the study conducted by Lawrence & Sheiham (1997). That study was selected because their study population consists of 12-year-old children who had no access to the fluoridated water supply, which is almost similar to the characteristics of the study population. The formula used for the estimation of sample size is given below (Chinna & Krishnan, 2009).

$$n = (Z_{\alpha/2} + Z_{\beta} / ES)^2$$

Where ES (Effect size) = 0.36, $Z_{\alpha/2} = 1.96$, $Z_{\beta} = 0.84$ (80%)

$$n = (1.96 + 0.84/ 0.36)^2$$

$$n = (2.8/ 0.36)^2$$

$$n = (7.77)^2$$

$$n = 60$$

The sample size of 60 participants was selected for each caries risk group (low, moderate and high). The minimum sample size required was 180, and by considering a 20% attrition rate, the sample size needed was at least 226 participants.

3.1.2 Sampling Methods

There were a total of 200 schools in Bhakkar. From these, seven schools (2 private and 5 public schools) with the highest student enrolment were conveniently selected to participate in this study to ease data collection and reduce costs. The lists of 11-12-year–old children from class 5, 6 and 7 were obtained from the register of each school. A total of 400 children were listed. Of these 300 children submitted the parental consent and were selected for a caries risk assessment. From these 300 children, 70 refused to participate, one child left school and three children were untraceable. The final sample stood at 226 subjects.

After obtaining parental consent participants, caries risk assessment was carried out using reduced Cariogram, and participants were allocated to the groups formed according to the caries risk level (low, moderate and high) of participants. The caries risk assessment was caries out a single point in time before baseline caries examination. The baseline examination was then performed, followed by follow-up examinations with a gap of six months between each assessment. At baseline and follow up assessments the caries measurements were carried out using DMFT and modified ICDAS. Before intra-oral assessment, a list of enrolled students containing only their name and class was provided to the school administration. On the day of the examination, a teacher nominated by the school administration called students from their classes according to the list provided.

To be eligible to participate in this study, a child should be between 11-12-years old, and able to understand basic instruction. Children below or above 11-12-years-old, with acquired physical disabilities, or who were receiving orthodontic treatment, were excluded. The age group of 11 to 12-years-old were selected because at this age participants have almost all permanent teeth erupted, except for the 3rd molars. Also, children of these ages can be reliably captured at schools (WHO, 2013). Furthermore, evidence has shown that at the age of 11 and 12, the risk of getting dental caries is higher because these children tend to have a high intake of cariogenic diet and are less focus towards oral hygiene (Macgregor et al., 1997; Gentry & Campbell, 2002; American Academy of Paediatric Dentistry, 2012).

In this study, participants were considered as dropout when school administration confirmed that the particular child who has participated in baseline examination has moved to a different school or has moved outside the city or when the participants were not willing to continue at any stage. If the school administration confirmed that participant was absent on the day of examination and reappeared on the next follow-up examination, they were considered as absentee. The actions taken to prevent drop out in this study includes obtaining contact information of children and reminding them through messages or a telephone call about the upcoming follow-up schedule.

Children who participated in this study were not informed of their caries risk level as participants identified as high caries risk may become more motivated to take care of his or her oral hygiene. In the case of the examiner, blinding was challenging to achieve because there was only one examiner involved. However, to prevent examiner bias on the day of intraoral examination a teacher nominated by the school administration helped to call out students randomly from the list provided. It was done to prevent the excessive assessment of the high-risk participants and to guarantee balance ascertainment of the outcome.

3.1.3 Ethical Approval

This study was approved by the Medical Ethics Committee of the Faculty of Dentistry, University of Malaya (Ref no: DF 71 CO1512/0072(P) (Appendix A). The permission to conduct this study in the government schools was obtained from the district education officer. For private schools, consent was sought from the administration of each school separately (Appendix B). At each follow-up visit, a written schedule for the next visit was submitted to the school administration. No treatment was provided to the participants during the study by the investigator. However, participants in need of emergency dental care were advised to visit the district headquarter hospital of Bhakkar city.

3.2 Research Instruments

The research instruments used in this study are the DMFT/DMFS index (WHO, 2013), the modified ICDAS index, the reduced Cariogram programme (which do not include saliva and microbial testing) and a diet diary. Radiographs were not used due to the constraints of the fieldwork setting and to prevent the risk of radiation exposure in the school settings.

3.2.1 Caries Assessment

The DMFT/DMFS indices were used to measure dental caries according to the WHO (2013) criteria. The DMFT/DMFS are the conventional methods employed globally to detect caries in epidemiological surveys, and this allows comparison to be made between countries. Under this method, only cavitated lesion is documented. Caries is recorded as present when there is an unmistakable cavity, the presence of undermined enamel, or a detectable softened floor or wall in the pits or fissure or on a smooth tooth surface. A tooth is considered filled with decay when it has one or more permanent restorations and one or more areas that are carious. A tooth extracted due to caries was considered missing (WHO, 2013).

The second method applied for caries assessment was the modified ICDAS index. It was selected because it is based on a detailed visual examination and records both non cavitated and cavitated carious lesions. Secondly, the use of the modified ICDAS does not require the drying of teeth with compressed air during the clinical assessment in field surveys. Lastly, the ICDAS index is gaining global interests, and its uses in Pakistan will allow the comparison of data in the future.

3.2.2 Reduced Cariogram

The reduced Cariogram was used due to the reduced application cost compared to the full Cariogram as it does not require saliva and bacterial testing and it is relatively easy to apply in the clinics and field surveys. The reduced Cariogram also has better sensitivity and specificity when compared to paper-based risk assessment tools (Gao et al., 2013).

To establish caries risk profile, information on the seven factors stated in the Cariogram programme is required namely caries experience, diet frequency, plaque amount, diet contents, fluoride use, clinical judgement and caries-related systemic disorders. The score range for each factor is from 0-3 and 0-2 in case of systemic diseases (Bratthall et al., 2004). The tools used to collect information regarding factors in Cariogram were selected according to the Cariogram manual (Bratthall et al., 2004). Cariogram factors and instruments used in this study to collect information for risk assessment are shown in Table 3.1.

Table 3.1: Factors in reduced Cariogram.

FACTOR	TOOL
Caries experience	DMFT Index
Diet Frequency Diet Content	Food Diary
Plaque	Loe & Sillness scale
Caries related Systemic disorders	Medical History
Clinical Judgment	The opinion of a dental examiner, 'clinical feeling'. A pre-set score of 1 comes automatically.
Fluoride use	Patient Interview

The explanations of scorings for each factor according to Cariogram are shown below.

For the caries experience, examiner judgement can be used to choose the right score on the basis of a previous epidemiological survey (Bratthall et al., 2004). For caries experience, the scores range from 0-3. According to the Pakistan national epidemiological survey, the mean DMFT score of 12-year-old children was 1.38 (Government of Pakistan, 2003). Depending on that if participants have a DMFT score of 1, code 1 was entered into the Cariogram, which is the code for better than normal DMFT score.

Code 0: DMFT score 0 (caries free)

Code 1: DMFT score of 1 and 2 (Better than normal)

Code 2: DMFT score of 3 and 4 (Normal for age group)

Code 3: DMFT score of 5 and 6 or more (Worse than normal)

To enter plaque levels were measured using Loe and Sillness plaque index as suggested in the Cariogram manual (Bratthall et al., 2004). The index teeth used to examine plaque levels were 16, 12, 24, 36, 32, and 44. For each index tooth, plaque score was estimated by adding the scores of the tooth surfaces (buccal, lingual, mesial and distal) and divided them by 4. Similarly, for an individual, the plaque score calculated for the six index tooth were added and divided by the total number of index teeth (Hiremath, 2011).

Code 0: Extremely Good, Plaque index < 0.4.

Code 1: Good, Plaque index 0.4-1.0.

Code 2: Less than good, Plaque index 1.1-2.0.

Code 3: Poor, Plaque index > 2.0.

The clinical judgement (perceptions of the examiner) factor is different from the other elements. It provides an opportunity for the examiner to express his/her ‘Clinical feeling’ and to see if the opinion differs from the program's inbuilt estimation. The default setting

Code 1 was overruled by the examiner if not satisfied with the scoring (Bratthall et al., 2004).

Code 0: The total impression of the caries situation, including social factors, gives a favourable view, more positive than what the Cariogram seems to indicate.

Code 1: The Cariogram shows the risk, according to the other values entered.

Code 2: If caries situation is worse than what Cariogram shows and the combined effect of dental caries including social factors, points in the direction of increased caries risk. Less than good compared to what the tests and the other factors seem to indicate.

Code 3: The combined effect of the caries situation, including social factors, is very bad and the investigator is sure that caries will occur in the coming year and would want the green sector to be minimal.

Diet content and diet frequency analysis was based on the information given in the 3-day diet diary. Codes used for this factor are given below: To allocate the scores of diet content the diet composition table of Pakistan was used.

Code 0: Very low intake of fermentable carbohydrates

Code 1: Low intake of fermentable carbohydrates/ non-cariogenic diet

Code 2: Moderately intake of fermentable carbohydrates

Code 3: Highly intake of fermentable carbohydrates/ high cariogenic diet

For diet frequency, the Cariogram provides codes 0-3.

Code 0: Maximum three sugar containing meals per day (including snacks).

Code 1: Maximum five sugar containing meals per day.

Code 2: Maximum seven sugar containing meals per day.

Code 3: More than seven sugar containing meals per day.

The content of sugars in food and drinks commonly found in Pakistani diet were identified from the food composition guideline by the Government of Pakistan (2001).

The types of sweet food consumed by the participants were observed from the filled diet diary than the sugar content of that food was checked from the food composition table, and the code in Cariogram was allocated to the diet content variable. Examiner judgement was used to select the appropriate code when the food was not in the food composition table.

Food items which were identified as cariogenic include candies, chocolates, Mithai (confectioneries), bakery products (cake & buns), soft drinks, sugar-sweetened milk and tea, bread, ice cream, biscuits, rice kheer/ banana kheer, lassi (sweetened yogurt drink), feerni, halwa suji/gajjar, zarda (sweet rice), shahi tukra (bread pudding), colored sugar water (roof afza), sheer khurma (vermicelli with sugar and milk), jams and preserved juices. The most common food items in the Pakistani diet, roti, chapatti and rice were identified as tooth friendly diet (Hiremath, 2011). The cariogenic food items not given here identified from Tinanoff, & Palmer, 2000; Moynihan, 2000; Sheiham, 2001; Moynihan & Petersen, 2004; Rinsky & Rinsky, 2008, Abdullah et al., 2008, Iftikhar et al., 2012 and Aziz & Hosain, 2014.

The information related to fluoride exposure was gathered by interviewing the participants. For fluoride program, Cariogram provides Codes ranging from 0-3.

Code 0: Maximum fluoride exposure based on frequent use of fluoride toothpaste, fluoride varnish, rinsing and tablets.

Code 1: Infrequent use of fluoride toothpaste, fluoride varnish, rinsing and tablets.

Code 2: Use of fluoride toothpaste only.

Code 3: Not using any fluoride measures.

The factor of the general disorder factor has three codes:

Code 0: Healthy patients without any caries-related disease.

Code 1: Patient with a disease which can indirectly contribute towards high caries risk.

Code 2 was scored for bedridden patients or taking medication which can affect the saliva secretion.

3.2.3 Equipment and Instruments

The equipment used in this study includes an adjustable portable dental chair and the instruments used for intraoral examination were mouth mirror, ball ended periodontal probes, tweezers, LED headlight illumination mounted on dental loupes and cotton roll/gauze.

3.3 Research Procedures

3.3.1 Pilot study

A pilot study was conducted to evaluate the acceptability of the research instruments, to familiarise a researcher with the study instruments and procedures, and to measure the time required to complete the procedures. In this study, a three-day prospective diet diary was used to record diet content and frequency of sugar intake (Appendix C). This method was selected because there is less measurement error, provide direct observation of what is eaten, and use conventional household measures such as a spoon, cups (Burrows et al., 2010). It was pre-tested on 20 school children to assess the ease of use, clarity and readability of items in the diet diary. These children were not a part of the main study.

The food diary used at dental clinics in the University of Malaya was adopted. This diet diary has been face and content validated by the dental public health academics at the University of Malaya. It was then translated from English to the Urdu language by two professionals who had a post-graduate degree in Public Health and who were fluent in both English and Urdu languages.

Clear instructions were imparted to the participants on how to fill up the diet diary. They were requested to fill the information on all food and beverage intake for three days (inclusive of a weekend and two weekdays). In addition to that, they were asked to record the time the food was taken (which would indirectly reflect whether the intake was at home or school), the amount ate or drank, and the time of their last meal before bedtime. The children were asked to return the diet diary after three days, during which records were examined, and a brief interview of participants was conducted to verify the accuracy of data provided.

Intra-oral examination was conducted with the children seated on a portable dental chair. The trained dentist performed inspections using LED headlight illumination mounted on dental loupes. Tooth assessment was initiated from the back of the upper right quadrant. First, mesial tooth surface was examined followed by occlusal, distal, buccal and lingual surfaces. Cotton rolls were used to dry tooth surface for the examination of non-cavitated lesion, and a ball ended periodontal probe was used to remove plaque on a tooth surface.The DMFS and modified ICDAS were applied to record dental caries. The DMFS index was employed first to all children, followed by the modified ICDAS index with a time gap of 30 minutes.

Out of the 20, only three children failed to submit diet diaries. The data of 17 children were inserted in the Cariogram to assess caries. A total of five children were identified as having high caries risk, two children had the intermediate caries risk, and ten children were classified as low risk to caries. The time spent on each participant during intraoral examination was approximately 10 minutes. No negative feedback was received from those who filled up the diet diaries. A slight modification was made to the diet diary to allow participants to enter the day and date at which food was taken. The number of eating or drinking occasions containing sugars at meals or between meals was assessed by the information obtained in the diet diary. Intake of two portions of sugary beverage or food within an eating event was counted as one occasion. From these data, the content of diet and frequency of sugar intake was used for further analysis.

3.3.2 Calibration

A single examiner (Muhammad Taqi) underwent training and calibration procedures for the modified ICDAS, DMFS and the plaque index. Training for the modified ICDAS index, with regards to the caries coding procedure, was provided by the ICDAS Task Force Committee member based at the Faculty of Dentistry, University Malaya. After training exercise, a calibration process was carried out over two days with a time interval of one week. The ICDAS codes for the 62 mounted teeth used in the calibration process have been validated by the aforementioned taskgroup. Teeth were recorded as follows: 0: sound; 1: first visual change in enamel seen after drying; 2: distinct visual change in enamel; 3: localised enamel breakdown; 4: underlying dark shadow from dentine; 5: distinct cavity with visible dentine; 6: extensive distinct cavity with visible dentin (Sebastian et al., 2015). The intra-examiner reliability for the ICDAS index was assessed using Cohen's weighted kappa. The inter-examiner kappa value achieved was 0.69, and the intra-examiner kappa value was 0.82 indicating a substantial agreement (Banting et al., 2009).

The calibration for the DMFS index was performed on 20 participants over a period of two days. These participants were not included in the main study. The calibration process as recommended by WHO (2013) was employed. The intraoral examinations were performed in the school premises with the subjects seated on the dental chair. Based on the WHO method, teeth were recorded as having decayed / frank cavitation (D), missing (M), filled with dental restoration (F), and sound (0). The intraexaminer reliability reached by the examiner was 0.88, indicating a substantial agreement (WHO, 2013).

The intra-examiner calibration for plaque index was conducted on 20 participants, and these participants were not included in the main study. The washout period of 2 hours was used between both examinations. Based on Loe & Sillness scale, tooth surfaces were recorded as follows: 0: no plaque, 1: a film of plaque adhering to the gingival margin, 2: moderate accumulation of plaque in gingival pocket visible to naked eye, 3: the abundance of soft deposit in a gingival pocket and adjacent tooth structure. A total of 560 surfaces were examined. The intra-examiner reliability reached by the examiner was 0.64, which is acceptable for research purposes (McHugh, 2012).

The post-study reliability was assessed by conducting oral examinations twice on 25 participants with a washout period of 4 days. The intra-examiner reliability was estimated by using Cohen's weighted kappa. The intra-examiner reliability reached by the examiner was 0.88 for DMFS and 0.66 for ICDAS II indicating a substantial agreement (WHO, 2013; Banting et al., 2009).

3.3.3 Teeth inclusion and exclusion criteria

Inclusion at baseline

- Teeth with sound surfaces, non cavitated and cavitated lesion, filled or filled with recurrent decay.
- Un-erupted teeth/ congenitally missing teeth and impacted teeth were considered as sound.

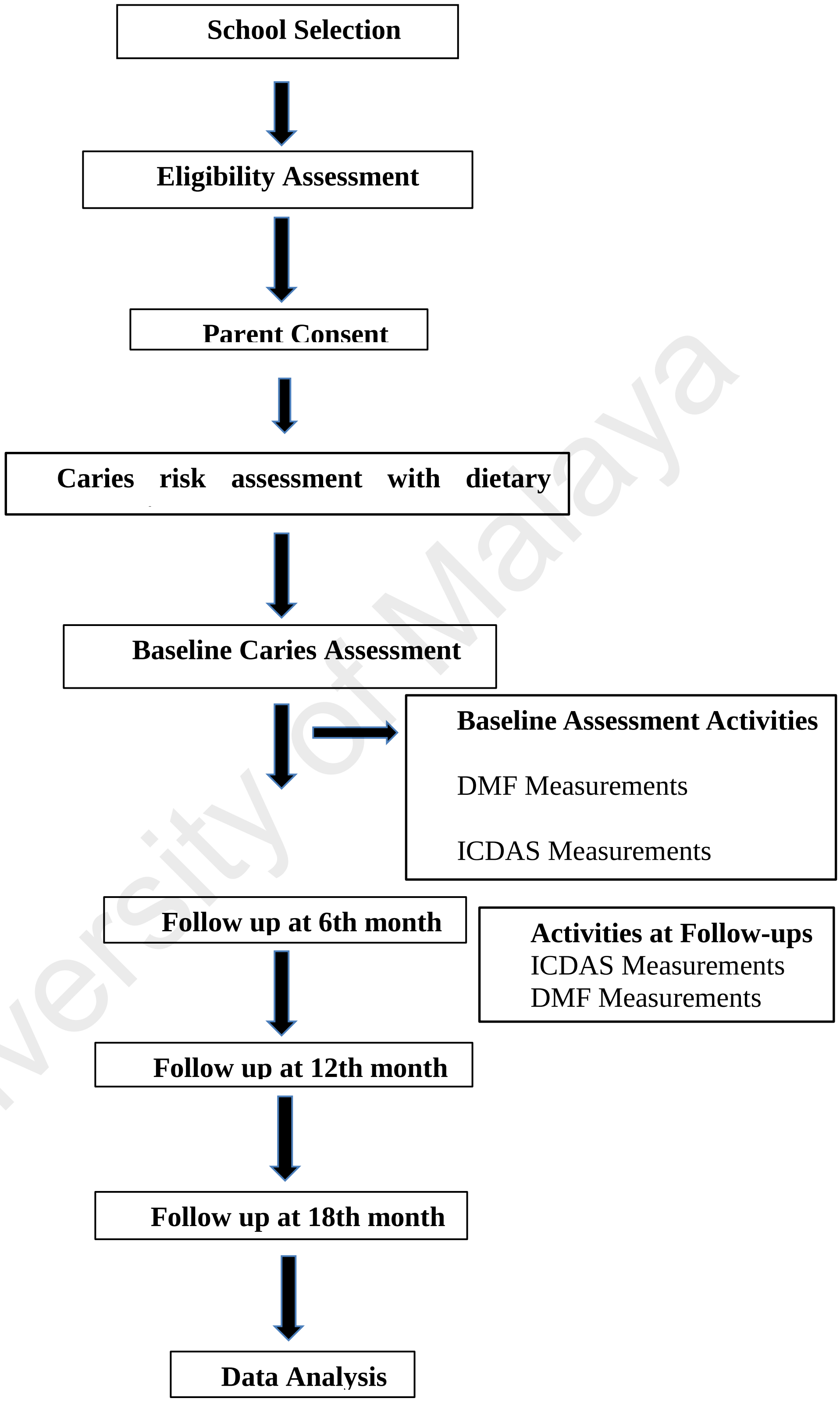
Exclusion at baseline and follow up

- Teeth missing due to reason other than caries for example extraction due to orthodontic treatment at follow-up.
- Tooth surfaces with fixed orthodontic appliances at baseline.
- Tooth surface which was recorded sound at baseline but had fixed orthodontic appliances at follow up will be excluded.

Inclusion at follow up

- Tooth surface diagnosed as sound at baseline but had a non-cavitated lesion, cavitated lesion, restorations or fissure sealants at follow-up.
- Tooth surfaces which were filled with restorations at baseline but had recurrent decay at follow-up.
- Tooth surfaces which had non cavitated and cavitated lesion at baseline, but appeared filled or missing due to caries at follow up.
- Tooth surfaces which had a non cavitated lesion at baseline and appeared sound or had cavitation at follow-up.

3.3.4 Study flow chart



3.4 Statistical Software and Techniques

The multiple imputations were performed using Stata version 14 according to the guidelines of Marchenko & Eddings (2011). Data from this study were analysed using the Statistical Package for Social Sciences version 17. The estimation of weighted Kappa was performed using MedCalc statistical software version 18.5 (MedCalc Software, 2016).

3.4.1 Analysis for multiple imputations

As mentioned previously, data was collected at four points in time (Baseline, follow-up 1, 2, and 3). Data of complete cases, absentee and drop out was entered in the software. Study variables such as age, gender, residence, school type, caries risk level, and baseline modified ICDAS scores were used as predictors for multiple imputations. To evaluate the assumption that data were missing at random, the difference between individuals with complete and incomplete data was measured using Chi-square analysis. The chained equation was applied to impute missing values by the predictive regression model (Royston, 2005). After the imputation to evaluate whether the variables included in the imputation model makes the missing at random assumption plausible, the difference between the distributions of imputed, observed and completed data values were evaluated by generating plots. The plots were generated separately for each follow-up (plot 4.1-4.6) (Appendix E).

3.4.2 Estimation of caries increment

Caries increment was measured using Modified Beck's method or adjusted caries increment (ADJCI) given by Ismail et al., 2011. The ADJCI was selected because it can measure caries increment among both cavitated and non-cavitated lesions and allows for the reversal's adjustment. The unit of observation used in this study is the tooth surface, and a score is given based on their transition. As previously mentioned, in this study 0 was assigned to the transitions associated with missing teeth due to caries to prevent overestimation of increment.

The transition and their scorings are adopted from Ismail et al., (2011).

Progression (Score +1)

- Progression from the sound (S) to non cavitated decay (D_{nc}).
- Progression from the sound (S) or non cavitated decay (D_{nc}): all progression cases were given score one except transition to missing (M).
- Progression from non cavitated decay associated with filling (F_{dnc}) to cavitated decay (D_c) and, cavitated decay associated with filling (F_{cd}).

2. Regression (Score 1)

- Regression from non-cavitated decay (D_{nc}) or cavitated decay (D_c) to sound (S).
- Regression from filled (F) to sound (S).
- Regression from non-cavitated decay associated with filling (F_{dnc}) to sound (S).
- Regression from cavitated decay associated with filling (F_{cd}) to sound (S), or non-cavitated decay associated with filling (F_{dnc}).

3. No progression nor regression (score of 0)

- No change in the caries status between baseline and follow-up caries assessment.
- The transition from missing (M) tooth surface regardless of subsequent caries assessment.

- The transition from cavitated decay (D_c) or cavitated decay associated with filling (F_{cd}) will receive a score of 0 except reversal.

Caries increment was calculated at two cut-offs D_TMFS (non-cavitated plus cavitated lesion/A-6) and D_CMFS (cavitated only / 3-6) as shown in Table 3.2.

Table 3.2: Application of Beck's formula to compute caries increment (Adopted from Ismail et al., 2011)

	Progression		Regression		No Progression / No Regression	
	Baseline	Follow up	Baseline	Follow up	Baseline	Follow up
D_TMFS	S S S D_{nc}, F_{dnc}, S, D_{nc}, D_c ,F, F_{dnc}, F_{cd},	D_{nc}, F_{dnc} D_c, F_{cd} F D_c, F_{cd} M	D_{nc}, F_{dnc} D_c, F_{cd}, D_c, F_{cd} F	S S D_{nc}, F_{dnc}, S	D_{nc} , F_{dnc} D_{nc} , F_{dnc} D_c , F_{cd} D_c , F_{cd} F F F M	D_{nc}, F_{dnc} F D_c , F_{cd} F F D_{nc}, F_{dnc} D_c, F_{cd} M
D_cMFS	S S S D_{nc}, F_{dnc} S, D_{nc}, D_c,F, F_{dnc}, F_{cd}	D_c, F_{cd} F F_{cd}, D_c D_c, F_{cd}, M	D_c, F_{cd} D_c, F_{cd} F F_{dnc}	S D_{nc} S S	D_c, F_{cd} D_c, F_{cd} F F F F_{dnc} M	D_c, F_{cd} F F F_{dnc} F_{cd}, D_c F M

S = sound teeth, D_{nc} = non-cavitated decay, D_c = cavitated decay, F_{dnc} = Non-cavitated decay associated with filling, F_{cd}= Cavitated decay associated with filling, F = filled, M = missing, D_TMFS = Cavitated and non cavitated decay, D_CMFS = Cavitated decay only

Table 3.3 shows a hypothetical illustration of adjusted caries increment estimation at child level on cut-offs for both baseline and follow-ups data. At both cut-offs the count of surfaces with progression, regression and no progression nor-regression were inserted into the formula given by Ismail et al., 2011 to calculate the increment at child level as shown below.

$$\text{ADJCI} = \frac{\text{Progression} \times \text{no progression nor regression}}{\text{Regression + no progression nor regression}}$$

Table 3.3: Hypothetical illustration of adjusted caries increment estimated at child level

Cut-off	Progression		Regression		No progression nor regression		Increment
	Baseline	Follow Up	Baseline	Follow up	Baseline	Follow up	
D_TMFS	S 1 S1	D_{nc} 1 D_C 1	D_{nc} 2 D_C 2	S 2 S 2	D_{nc} 3 D_C 1	D_{nc} 3 D_C 1	2
Total	4		8		8		
D_CMFS	S 1	D_C 1	D_C 2	S 2	D_C 1	D_C 1	0.6
Total	2		4		2		

ADJCI (D_TMFS)= 4 ×8/8+8= 2

ADJCI (D_CMFS) = 2× 2/4+2=0.6

3.4.3 Estimating the predictability of reduced Cariogram

In this study, the prediction accuracy of reduced Cariogram was measured by developing Receivers Operating Characteristic curve (ROC). Youden's analysis was used to estimate the optimal cut-off point at which reduced Cariogram demonstrate the sensitivity and specificity. The ROC can show the true positive rates against the false positive rates at various cut-off points, above which the test will consider as abnormal and below which the test will be considered as normal (Ha, 2011). The ROC provides extensive information, which includes

1. The cut-off point between sensitivity and specificity.

2. The accuracy of the test when the curve is above the diagonal line and closer to the left-hand border of the ROC curve.

3. The poor test accuracy when the curve is closer to the diagonal line.

In Figure 3.2 different ROC curves are shown indicating the good, excellent and worthless test. The area under the curve above the diagonal line measures the accuracy. The overall diagnostic ability of a test can be assessed by calculating the area under the curve. The model which has 1.0 of the area under the curve indicates excellent discriminatory ability. On the other hand, a model which has 0.50 or less area under the curve indicates that the test fails to discriminate between individuals with or without outcome (Linden, 2006).

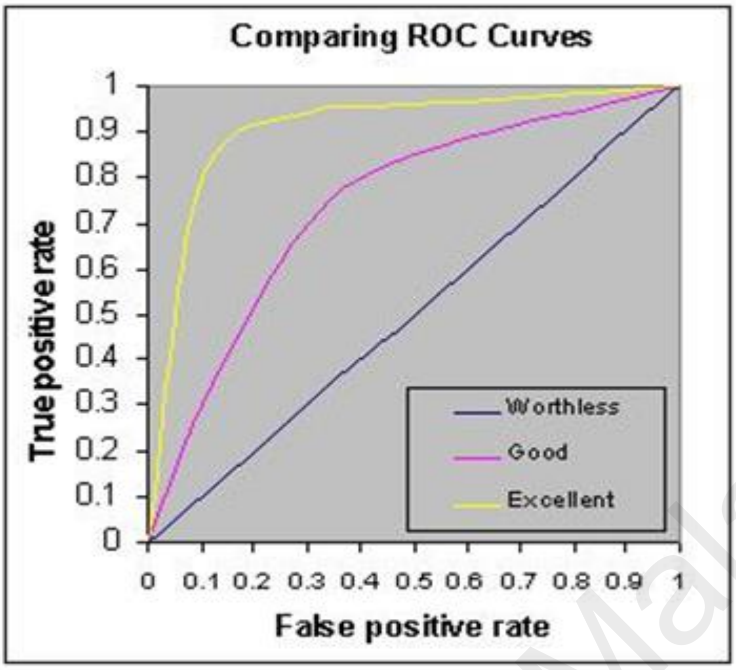


Figure 3.5: Receivers Operating Characteristic curve adopted from (Ha, 2011).

3.4.4 Statistical Analysis

For the statistical analysis, a significant cut-off value was set at <0.05. Descriptive analysis was conducted to estimate the response rate at baseline and at each follow-up, and to estimate the number of children who attended the examinations. Cross-tabulation was conducted to assess the frequency of participants according to socio-demographic characteristics. Chi-square test was conducted to determine the association between sociodemographic factors and the occurrence of the carious lesion. The independent sample t-test was performed to estimate the mean difference in the number of sound teeth, ECL, and caries history between sociodemographic variables.

For objective 1: To determine the caries risk levels using reduced Cariogram and caries risk predictors in 11-12-year-old Pakistani children.

Descriptive analysis was conducted to estimate the distribution of children according to chance to avoid caries and mean DMFT score at each follow-up. The cross-tabulation was conducted to estimate the proportion of children and distribution of variables scores occurrence according to the caries risk assessed. Chi-square test was used to determine the association between sociodemographic factors and levels of caries risk. The same test was used to find the association between caries risk levels and mean DMFT score, plaque score and frequency of sugar intake. The variables plaque score, frequency of sugar intake and DMFT were categorised according to the ranges provided in Cariogram manual (Brathall et al., 2004)

The independent sample t-test was conducted to analyse the variation in frequency of sugar intake among children at different location and timing. The dependent sample t-test was performed to compare the difference in caries experience and pattern and frequency of cariogenic food intake. Linear and multiple regressions were conducted to determine the factors that can predict caries risk and caries experience. The dependent variables used in regression analysis were caries risk categories and scores of early carious lesions and the DMFT scores.

For objective 2: To assess the agreement between modified ICDAS and the WHO method on caries detection rate.

Cross-tabulation was conducted to estimate the relationship between the scores for the sound and decayed component obtained using modified ICDAS and WHO criteria at the tooth surface level. Wilcoxon test was applied to compare the decayed teeth identified by the WHO criteria and modified ICDAS at all cut-offs. McNemar test was employed to compare the caries prevalence calculated by the WHO criteria and modified ICDAS at all cut-offs. The weighted Kappa scores were used to estimate the agreement between the WHO methods and modified ICDAS.

For objective 3: To determine the predictability of reduced Cariogram by comparing the caries risk profile established at baseline with the caries increment on follow-up at 6, 12 and 18th month.

One-way ANOVA analysis was performed to evaluate the mean caries increment at all follow-ups according to chance to avoid caries and according to the risk levels. To assess the performance of reduced Cariogram in predicting caries increment the receivers operating characteristics (ROC) analysis was performed using risk levels established at baseline and the caries increment after 6, 12, and 18 months as a test variable. The cut-off for the estimation of sensitivity (Se), specificity (Sp) was calculated by performing the Youden's analysis.

For objective 4: To determine the rate of caries progression over an 18-month period using WHO method & ICDAS and to recommend an appropriate dental recall interval.

Repeated measure ANOVA with post hoc test using Bonferroni correction was used to compare the mean caries increment within each risk level. The percentage change was estimated manually using the difference between old and new mean increment values and dividing the outcome by the old value and multiplied by the 100.

3.4.5 Study Variables

Table 3.4: Variables included in the study for statistical analysis

S.no	Variables	Operational Definition	Scale	Unit of Measurement
1	Age of child	Age of last birthday	Continuous	Mean age
2	Gender of child	Sex as stated in the school register	Nominal	1.Male 2. Female
3	Residence	Participant place of dwelling as stated in the school register	Nominal	1.Urban 2.Rural
4	School		Nominal	1.Government School 2.Private school
5	DMFT/DMFS	Sum of decayed and filled teeth/surfaces due to caries based on WHO caries diagnostic criteria (WHO, 2013)	Nominal	0.Sound 1.Decayed teeth/Filled with decay 2. Filled no decay 3. For Extraction
6	Modified ICDAS	International Caries Detection and Assessment System	Ordinal	0: No evidence of caries A: Initial Caries 3:Localised enamel break down due to caries with no visible dentin 4: Underlying dark shadow from dentin 5: A distinct cavity with visible dentin 6:Extensive distinct cavity with visible dentin

7	Plaque Score Silness-Löe plaque	Participant score for the measurement of the oral hygiene based on recording both soft debris and mineralized deposits on the teeth identified at baseline	ordinal	0: Extremely good oral hygiene, Plaque Index, PI < 0.4 1:Good oral hygiene, PI = 0.4-1.0 2: Less than good oral hygiene, PI = 1.1- 2.0 3:Poor oral hygiene, PI > 2.0
8	Prevalence of caries	The proportion of child with caries in a period of time (2016-2017)	Continuous	Percentage
9	Adjusted caries increment among cavitated lesions only	The difference of mean caries scores at baseline and after 3 follow-ups	Continuous	Mean difference
10	Adjusted caries increment among non-cavitated plus cavitated lesions	The difference of mean caries scores at baseline and after 3 follow-ups	Continuous	Mean difference
11	Sugar intake	The frequency of sugar intake by the participant identified at baseline	Continuous	0: Maximum three meals per day (including snacks) 1: Maximum five meals per day 2: Maximum seven meals per day 3: More than seven meals per day
12	A chance to avoid caries	The proportion of participants with a chance to avoid caries identified at baseline	Continuous	Percentage
13	Risk level	Level of caries risk identified at baseline	Nominal	1: Low Risk 2: Medium Risk 3: High Risk

CHAPTER 4: RESULTS

4.1 Outcome of multiple imputations

The number of children who attended the examinations is shown in Table 4.1. A total of 147 (65%) children attended all four examinations. In this study the proportion of missing data was 36.2% due to which the power of the sample size was reduced to 70%.

Table 4.1: Variables included in the study for statistical analysis

Examination stage	Numbers of children who attended examinations n%
B,1,2,3	147 (65)
B,1,2	2 (0.8)
B,1,3	8 (3.5)
B,2,3	20 (8.8)
B,3	2 (0.8)
B,2	0 (0)
B,1	11 (4.8)
B	30 (13.2)
1,2,3	5 (2.2)
2,3	0 (0)
1,3	1 (0.4)
1,2	0 (0)
Total	226 (100)

B: Baseline examination, 1: First follow-up, 2: Second Follow-up, 3: Third Follow-up

By comparing the distribution of the main predictors (gender, residence, school type, and caries risk levels), the difference between individuals with complete and incomplete data was estimated using Chi-square analysis (Appendix D). The result reveals a significant difference between observed and missing individuals for ‘school type’. However, gender, school type and the main variables of interest which is caries risk levels showed a no significant difference and fulfilled the assumption for data missing at random. According to Kang, if the assumption for data missing completely at random (MCAR) was not satisfied, and the power of the study was reduced, the statistical analysis of only complete cases can produce bias (Kang, 2013). In this study, the mechanism of missing data was both missing at random, and missing completely at random, and the pattern of missing data was monotone. For statistical analysis, a single imputed data set was created by performing twenty imputations using chained equation cycles.

The plots which were created to evaluate whether the variables included in the imputation model makes the missing at random assumption plausible showed a difference in the distribution of imputed, complete and observed values which indicate that data was missing at random (MAR) (Appendix E) (Marchenko & Eddings, 2011).

4.2 Response rate

The list of 11-12-year–old children from class 5, 6 and 7 were obtained from the register of each school. A total of 400 children were listed. Of these only 300 children obtained parental consent. However, due to reasons shown in Table 4.2, the final sample size stood at 226 children. These children attended the caries risk assessment procedure conducted before baseline assessment.

Table 4.2: Participant response rate at enrollment

Enrolment	400
Signed Consent	300
Decline to participate	70
Left school	4
Final sample size	226
Response rate	97%

At the time of caries risk assessment all 226 children were present. On baseline examination, a total of 220 children were present, and eight were absent, leaving a follow-up rate of 96%. A total of 174 children attended the first follow-up examination, twenty-two children were absent, and 30 children were excluded due to dropouts, leaving a follow-up rate of 77% (Table 4.3). Similarly, 174 children attended the second follow-up examination. However, eleven children were absent, and 41 were excluded due to dropouts, leaving a follow-up rate of 77%. In the last follow-up, 183 children were present, no participant was missing, and 43 children were excluded due to dropouts, giving a follow-up rate of 81% as shown in Table 4.3.

Table 4.3: Follow-up rate and dropout rate at risk assessment, at baseline and follow-up examinations.

	Number of Examination	Number of enrolled participants	Total	Low (n)	Medium (n)	High (n)
1	Risk assessment	226	226	90	69	67
2	Baseline caries assessment	Attendees	220	86	67	65
		Absentees	6	2	2	2
		Total Response rate	218/226 = 97%			
3	1st Follow up	Attendees	174	75	49	50
		Absentees	22	7	8	7
		Dropouts	30	8	12	10
		Total Response rate	174/226 = 77%			
4	2nd Follow up	Attendees	174	74	49	51
		Absentees	11	3	5	3
		Dropouts	41	13	15	13
		Total Response rate	174/226 = 77%			
5	3rd Follow up	Attendees	183	75	54	54
		Dropouts	43	15	15	13
		Total Response rate	183/226 = 81%			

4.3 Sociodemographic characteristics

The sociodemographic distribution of participants is shown in Table 4.4. Most of the children were male (54.5%), and the majority of them were from the urban residences (82.4%). The number of children from publicly funded schools was higher (65.9%) than the children from privately funded schools (34.1%).

Table 4.4: Sociodemographic characteristic of the study sample at baseline (N=226)

Sociodemographic background		n(%)
Gender	Male	123(54.5)
	Female	103(45.5)
Residence	Urban	186(82.4)
	Rural	40(17.6)
School type	Public funded	149(65.9)
	Private funded	77(34.1)

The distribution of children according to the occurrence of carious lesion is shown in Table 4.5. Within the sample, 51% of children had ECL, and 24% of children had established carious lesions. Children from government-funded schools had significantly higher (73%) caries level compared to children from private-funded schools (27%) ($p=0.03$). Majority (73%) of participants from public schools were identified with caries, as compared to 27% of participants from private schools. On the other hand, between gender, location of residence and caries history, no significant association was observed.

Table 4.5: The distribution of subjects according to the prevalence of the carious lesion at baseline (n=226).

Variable	n (%)								
	Caries		p	ECL		p	D_{4-6}MFT		P
	Yes	No		Yes	No		Yes	No	
All subjects	169(75)	57(25)		115(51)	111(49)		54(24)	172(76)	
Boys	90(53)	33(58)	0.54	63(55)	60(54)	0.91	27(50)	96(56)	0.45
Girls	79(47)	24(42)		52(45)	51(46)		27(50)	76(44)	
Public School	124(73)	33(58)	0.03	86(75)	71(64)	.085	38(70)	119(69)	0.86
Private School	45(27)	24(42)		29(25)	40(36)		16(29)	53(31)	
Urban	139(82)	47(82)	0.97	94(81)	92(83)	0.82	45(83)	141(82)	1.0
Rural	30(18)	10(18)		21(19)	19(17)		9(17)	31(18)	

Caries: Individuals with cavitated plus non-cavitated lesion (Modified ICDAS Code A &6)
ECL: Individuals with non-cavitated lesions only (Modified ICDAS Code A &3)
D_{4-6}MFT: Individuals with cavitated lesions only (Modified ICDAS Code 4,5 &6)
Chi-square Test

The comparison of sociodemographic variables with the mean number of sound and carious teeth at baseline is shown in Table 4.6. The mean ECL score was 3.0±1.8, which was higher than the mean D_{4-6}MFT score of 1.4±0.9. Despite the no statistically significant difference, the mean number of sound teeth and mean ECL score was higher among girls. Those who lived in the rural area had a statistically higher mean number of sound teeth (25.9±2.8) compared to those who live in rural areas (22.0±5.4) (p=0.04). Mean ECL scores in children of public school were statistically higher (3.1±1.9) compared to their private school counterparts (2.3±1.3) (p=0.04).

Table 4 6: Comparison of sociodemographic variables with the mean number of sound and carious teeth at baseline.

Variable	Mean number of sound and carious teeth					
	Sound	p	ECL	p	D_{4-6}MFT	p
All subjects	22.7(5.2)		3.0(1.8)		1.4(0.9)	
Boys	22.0(5.2)	0.24	2.9(1.9)	0.85	1.4(1.0)	0.55
Girls	23.7(5.2)		3.0(1.8)		1.3(0.7)	
Public School	22.6(5.5)	0.91	3.1(1.9)	0.04	1.4(1.0)	0.86
Private School	22.8(5.1)		2.3(1.3)		1.3(0.6)	
Urban	22.0(5.4)	.004	2.8(1.7)	0.14	1.3(0.8)	0.34
Rural	25.9(2.8)		3.5(2.2)		1.6(1.0)	

Caries: Individuals with cavitated plus non-cavitated lesions
ECL: Individuals with non-cavitated lesions only (Modified ICDAS Code A &3)
D_{4-6}MFT: Individuals with cavitated lesions only (Modified ICDAS Code 4,5 &6)
Independent Sample t-test

4.4 Risk assessment using reduced Cariogram

The comparison of sociodemographic variables against caries risk groups, as categorised by the Cariogram programme, is shown in Table 4.7. At caries risk assessment, reduced Cariogram identified about 39.8% of children as low risk, 30.5% as medium risk and 29.7% as high risk. Among low-risk participants, out of 90 participants a significantly higher number of children were from the private schools (76.6%) as compared to the government-funded schools (20.8%) ($p<0.0001$).

Table 4.7: Comparison of sociodemographic variables against risk group at baseline

Sociodemographic background	Caries risk levels according to Cariogram, n(%)			p-value
	Low	Medium	High	
All subjects	90 (39.8%)	69 (30.5)	67 (29.7)	
Gender				
Male	49 (39.8)	38(30.9)	36(29.3)	0.98
Female	41(39.8)	31(30.1)	31(30.1)	
Residence				
Urban	77(41.4)	53(28.5)	56(30.1)	0.34
Rural	13(32.5)	16(40)	11(27.5)	
School type				
Public funded	31(20.8)	63(42.3)	55(36.9)	.0001
Private funded	59(76.6)	6(7.8)	12(15.6)	

Chi-square test

The comparison of caries experience with caries risk levels reveals that all children (100%) categorised in the low-risk group had no caries; while about 88% and 28% of children in the medium and high caries risk levels were caries free respectively (Table 4.8). The intake of fermentable carbohydrates was higher in children with medium risk (76.8%) as compared to the children with high (53.7%) and low (44.4%) caries risk. Similarly, the intake of sugar-containing meal per day was higher in medium risk children (18.8%) as compared to the children with low (5.6%) and high (10.4%) caries risk (Table 4.8). In the case of oral hygiene, the majority of low-risk children (72.2%) had good oral health as compared to children with medium (44.4%) and high (37.3%) caries risk. When access to fluoride was compared, the majority of low-risk children (97.8%) had access to fluoride toothpaste as compared to the children with medium (88.4%) and high (77.6%) caries risk (Table 4.8).

Table 4.8: Scores of Cariogram variables allocated in each risk level at baseline

Variables		Low Risk n(%)	Medium Risk n(%)	High Risk n(%)
Caries Experience (DMFT)	Code 0: Caries Free	90 (100)	61 (88.4)	19 (28.4)
	Code1: Better than normal	0	8(11.6)	43(64.2)
	Code2: Normal for age group	0	0	4(6.0)
	Code3: Worse than normal	0	0	1(1.5)
Systemic Disease	Code 0: Healthy patients without any caries-related disease.	90(100)	69(100)	67(100)
	Code 1: Patient with a disease which can indirectly contribute towards high caries risk.	0	0	0
	Code 2 was scored for bedridden patients or taking medication which can affect the saliva secretion.	0	0	0
Diet Content	Code 0: Very low intake of fermentable carbohydrates	0	0	0
	Code 1: Low intake of fermentable carbohydrates/ non-cariogenic diet	49(54.4)	14(20.3)	31(46.3)
	Code 2: Moderately intake of fermentable carbohydrates	40(44.4)	53(76.8)	36(53.7)
	Code 3: Highly intake of fermentable carbohydrates/ high cariogenic diet	1(1.1)	2(2.9)	0

Table 4.8 continued

Sugar Frequency	Code 0: Maximum three sugar containing meals per day (including snacks).	50(55.6)	15(21.7)	26(38.8)
	Code 1: Maximum five sugar containing meals per day.	35(38.9)	40(58.0)	33(49.3)
	Code 2: Maximum seven sugar containing meals per day.	5(5.6)	13(18.8)	7(10.4)
	Code 3: More than seven sugar containing meals per day.	0	1(1.4)	1(1.5)
Plaque Level	Code 0: Extremely Good (PI <0.4)	0	0	0
	Code 1: Good (PI 0.4-1.0)	65(72.2)	31(44.4)	25(37.3)
	Code 2: Less than good (PI 1.1-2.0)	25(27.8)	37(53.6)	41(61.2)
	Code 3: Poor (PI>2.0)	0	1(1.4)	1(1.5)
Fluoride Programme	Code 0: Maximum fluoride exposure based on frequent use of fluoride toothpaste, fluoride varnish, rinsing and tablets.	0	0	0
	Code 1: Infrequent use of fluoride toothpaste, fluoride varnish, rinsing and tablets.	2(2.2)	1(1.4)	0

	Code 2: Use of fluoride toothpaste only.	88(97.8)	61(88.4)	52(77.6)

Table 4.8 continued

	Code 3: Not using any fluoride measures.	0	7(10.1)	15(22.4)
Clinical Judgement	Code 0: The total impression of the caries situation, including social factors, gives a favourable view, more positive than what the Cariogram seems to indicate.	1(1.1)	1(1.4)	2(3.0)
	Code 1: The Cariogram shows the risk, according to the other values entered.	88(97.8)	64(92.8)	52(77.6)
	Code 2: If caries situation is worse than what Cariogram shows and the combined effect of dental caries including social factors	1(1.1)	4(5.8)	13(19.4)
	Code 3: The combined effect of the caries situation	0	0	0

The proportion of children and their caries experience according to their chance to avoid caries at baseline are shown in Table 4.9. About 30.1% of children had less than a 40% chance of avoiding dental caries, 30.5% with 40-60% chances to avoid caries, 22.1% had 61-80% chance to avoid caries, and 81-100% had 17.3% chance to avoid caries. Children who had less than 40% chances of avoiding caries had higher mean DMFT score (1.51±0.65) as compared to the children who had more than 40% chance of avoiding caries (1.33±0.57).

Table 4.9: Proportions of children and their caries experience with a chance to avoid caries in percentage at baseline.

Chance to avoid caries	0-20% Very high risk	21-40% High risk	41%-60% Medium risk	61%-80% Low risk	81%-100% Very low risk
n(%)	0(0)	68 (30.1)	69 (30.5)	50 (22.1)	39 (17.3)
Baseline DMFT (Mean±S.D)	0	1.51±0.65	1.33±0.57	0	0

The association between caries risk levels identified at baseline and mean DMFT scores, mean plaque score and mean frequency of sugar intake are shown in Table 4.10. The mean DMFT score in low-risk participants was zero. At baseline, children categorised in the high-risk groups had the highest mean DMFT score of 1.51, mean plaque score of 0.39 and mean frequency of sugar intake of 5.5. A significant association was found between caries risk levels and mean DMFT scores, plaque scores and frequency of sugar intake**.**

Table 4.10: Distribution of mean DMFT score, sugar intake and plaque according to risk levels at baseline.

Caries Risk	Mean Sugar Intake (S.D)	P value	Mean DMFT score (S.D)	P value	Mean Plaque score (S.D)	P Value
Low Medium High	4.2±0.4 5.0±0.8 5.5±1.1	.0001	0 1.33±0.51 1.51±0.65	.0001	0.31±0.21 0.37±0.15 0.39±0.15	.0001
Overall	5.2±3.2		1.49±0.63		0.35±0.18	

Chi-square Test

The frequency of sugar intake at different times and place at baseline is shown in Table 4.11. The overall mean frequency of dietary free sugar intake was 5.2±3.2 times per day. The mean frequency of dietary free sugar intake at home and weekdays was higher at 6.9±3.0 times per day, compared to the mean frequency taken at schools which was 2.9±1.6 times per day, and during weekends which was 2.8±1.5 times per day, but these findings were not statistically significant.

Table 4.11: Frequency of sugar intake at different times and place on the baseline

Time and place of sugar intake	Overall Mean (S.D)	Boys Mean (S.D)	Girls Mean (S.D)	P value	Urban Mean (S.D)	Rural Mean (S.D)	P value
Place							
Home	6.9(3.0)	6.8(2.8)	7.0(3.3)	0.92	6.8(3.0)	7.2(3.1)	0.82
School	2.9(1.6)	2.8(1.5)	3.1(1.7)	0.47	2.9(1.6)	2.8(1.6)	0.85
Total	5.2(3.2)	5.0(3.1)	5.3(3.3)	0.70	5.2(3.2)	5.3(3.4)	0.66
Time							
Weekend	2.8(1.5)	2.8(1.5)	2.8(1.6)	0.79	2.8(1.5)	2.8(1.6)	0.98
Weekdays	6.9(3.0)	6.6(2.8)	7.2(3.2)	0.21	6.8(3.0)	7.2(3.1)	0.45
Total	5.2(3.2)	5.0(3.0)	5.3(3.4)	0.31	5.2(3.2)	5.3(3.4)	0.64

Independent Sample t-Test, SD: Standard deviation

The mean number of sound and carious lesion according to the pattern and frequency of sugar intake at baseline is shown in Table 4.12. A significantly higher mean DMFT score was observed in children who consumed cariogenic food or drinks in between main meals (p=0.01) and within two hours before bedtime (p=0.04), as compared to children who did not do so. Children who consumed sugars less than four times a day and only during main meals had a higher mean number of sound teeth and a lower mean number of ECL, but these were not statistically significant.

Table 4.12: Mean number of sound and carious lesion according to the pattern and frequency of sugar intake at baseline.

	F	Sound Mean (S.D)	P value	ECL Mean (S.D)	P value	D_{4-6}MFT Mean (S.D)	P value
Daily intake of cariogenic food	>4 <4	22.5(5.2) 23.1(5.5)	0.69	3.0(1.9) 2.8(1.7)	0.51	1.4(1.0) 1.3(0.4)	0.51
Cariogenic food during main meals	No Yes	21.1(5.7) 23.4(4.9)	0.14	2.6(1.4) 3.0(2.9)	0.41	1.3(0.4) 1.4(1.0)	0.74
Cariogenic food between meal	No Yes	23.0(5.0) 21.4(6.1)	0.36	3.3(1.8) 2.9(1.8)	0.54	1.0(0) 1.4(0.9)	0.01
Cariogenic food 2 hr before bed time	No Yes	22.7(4.8) 22.7(5.5)	0.97	2.9(1.8) 3.0(1.9)	0.86	1.0(0.2) 1.6(1.0)	0.04

Dependent sample t-test

4.5 Caries risk Predictors

This analysis was conducted using data collected at the caries risk assessment. Univariate analysis of Cariogram variables that affect caries risk and variables of patterns and frequency of sugar intake that affect caries experience are shown in Table 4.13 and Table 4.14. The dependent variables used in regression analysis were caries risk categories and individual score of early carious lesion (ECL) and individual $D_{4-6}MFT$ score. The independent variables are shown in Table 4.13 and Table 4.14. The linear relationship was found between dependent and independent variables as shown in Figure 4.1 and Figure 4.2.

All variables show significant impact on caries risk profile and caries history except for place of residence as shown in Table 4.13, daily intake of cariogenic food, cariogenic food in main meals, cariogenic food between main meals as shown in Table 4.14. The variables show no significant impact in univariate analysis were excluded from the later analysis. In the case of early carious lesions (ECL), cariogenic food intake at bedtime shows no significant impact and excluded from the later analysis.

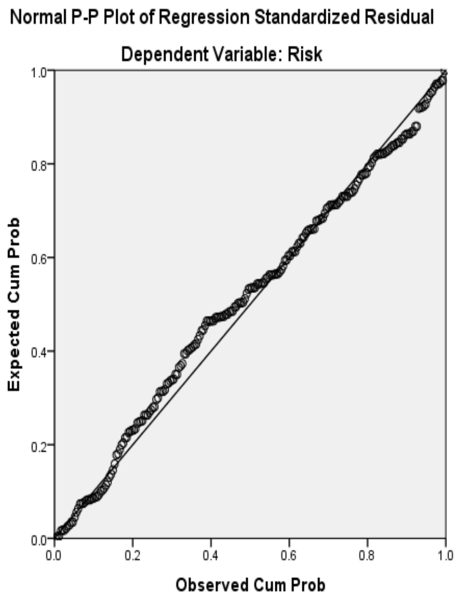


Figure 4.2: Scatter plot for normality of residuals in linear regression analysis using dependent variable caries risk.

Figure 4.3: Scatter plot for normality of residuals in linear regression analysis using D_{4-6}MFT as a dependent variable.Figure 4.4: Scatter plot for normality of residuals in linear regression analysis using dependent variable caries risk.

Table 4.13: Variables in univariate analysis of caries risk predictors

Variables	P value
Caries experience	0.000
Diet content	0.008
Frequency of diet	0.002
Plaque scores	0.000
Fluoride sources	0.000
Clinical judgement	0.002
Type of school	0.000
Place of residence	0.144

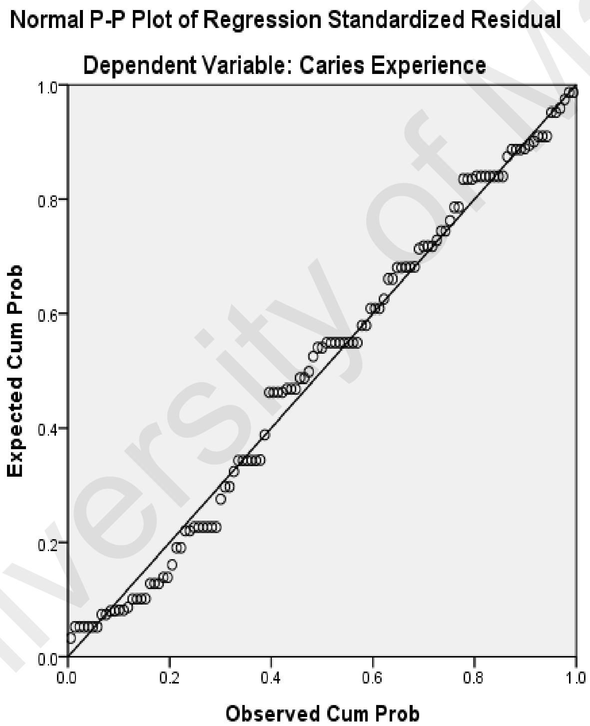


Figure 4.5: Scatter plot for normality of residuals in linear regression analysis using D_{4-6}MFT as a dependent variable.

Figure 4.6: : ROC curve at 6, 12 and 18 months.Figure 4.7: Scatter plot for normality of residuals in linear regression analysis using D_{4-6}MFT as a dependent variable.

Table 4.14: Patterns and frequency variables entered in the linear regression model for caries experience predictors.

Variables	ECL P value	D_{4-6}MFT p value
Daily intake of cariogenic food	0.40	0.67
Cariogenic food during main meals	0.32	0.70
Cariogenic food between meal	0.88	0.91
Cariogenic food before bed time	0.69	0.02

Linear Regression Analysis

The variables in the forward stepwise multivariate analysis are shown in Table 4.15 and Table 4.16. All significant variables from the univariate analysis were analysed in the forward stepwise multivariate analysis. The result revealed that the most relevant variable in caries risk prediction was previous experience of dental caries and consumption of cariogenic food before bedtime, which explains 40% and 70% of the caries risk respectively.

Table 4.15: Variables in forward stepwise multiple regression model.

Step	Variable	F	β	p	R^2
1	Caries experience	148.5	0.568	0.000	0.40
2	Fluoride program	136.1	0.342	0.000	0.55
3	School	131.1	-0.323	0.003	0.63
4	Clinical Judgement	113.4	0.180	0.000	0.67
5	Plaque scores	99.8	0.167	0.001	0.69
6	Diet Frequency	92.4	0.115	0.009	0.71
7	Diet content	82.3	0.102	0.000	0.72

F: F Statistics β: Beta Coefficient R^2: Adjusted R Square

Table 4.16: Regression analysis of significant variable

	F	β	P	R^2

Caries History	-	-	0.00	-
Cariogenic food before bed time	5.4	.30	0.02	0.7

F: F Statistics β: Beta Coefficient R^2: Adjusted R Square

4.6 Correlation between WHO (DMFS) and ICDAS methods

Three cut-off points were created to establish the correlation between WHO criteria and the modified ICDAS which includes: cut-off l (0 sound, A-6 as carious), cut-off 2 (0-A as sound, 3-6 as decayed) and cut-off 3 (0-3 as sound, 4-6 as decayed) respectively. The distribution of sound and carious lesions identified by the WHO and modified ICDAS methods at baseline are shown in Table 4.17. For the WHO method, score 0-A is for sound surfaces, and score 3-6 is for decayed surfaces. Both systems identified almost 97% of surfaces as a sound. Eighteen surfaces identified as carious by the WHO method were categorised as sound by modified ICDAS.

Table 4.17: Distribution of sound and decayed component obtained at baseline and follow-ups using modified ICDAS and WHO criteria at the tooth surface level at baseline**.**

WHO	Number of surfaces with modified ICDAS score						
	0	A	3	4	5	6	Total
Caries Free	22569	399	0	0	0	0	22968 (99%)
Caries Positive	18	0	174	55	57	24	328 (1%)

Total	22587 (97%)	399 (1.7%)	174 (0.7%)	55 (0.2%)	57 (0.2%)	24 (0.1%)	23296 (100%)

Statistically, there was no significant variation in the values of DMFS/DMFT and prevalence of dental caries by the WHO method as compared to the modified ICDAS at cut-off 2 as shown in Table 4.18. The mean ICDAS scores at cut-off 1 were 4.92±2.6 and 4.30±2.2, which were significantly higher than the DMFS and DMFT values. Conversely, the mean ICDAS score at cut-off 3 was 2.0±1.7 and 1.85±1.3 markedly lower than the DMFS and DMFT values. For the modified ICDAS at cut-off 1 and 3, the prevalence of caries was significantly higher (79.8%) and lower (37.2%) respectively compared to the WHO criteria. The average time spends on the application of modified ICDAS was 3.5±0.9 minutes as compared to 1.7±0.5 minutes when the WHO method was used ($p<.0001$).

Table 4.18: Comparison between WHO method (Mean±S.D) and the modified ICDAS on the prevalence of caries using cut-off scores 1, 2 and 3.

		ICDAS II cut-off-scores		
	WHO (Mean±S.D)	Cut-off 1 0 Sound A-6 decayed (Mean±S.D)	Cut-off 2 0-ASound 3-6 decayed (Mean±S.D)	Cut-off 3 0-3 Sound 4-6 decayed (Mean±S.D)
DMFS	3.28±2.5	4.92±2.6	3.21±2.3	2.0±1.7
P value[1]		.000	0.64	.002

DMFT	2.69±1.7	4.30±2.2	2.67±1.7	1.85±1.3
P value[1]		.000	0.70	.003
Prevalence (95% CI)	55.7 48.2 - 63.1	79.8 73.2 - 85.3	55.8 48.2 - 63.1	37.2 30.1 - 44.6
P value[2]		.000	1.0	.000

[1]ICDAS compared with WHO (Wilcoxon test) [2]ICDAS compared with WHO (McNemar test).

The comparison of intra-examiner reliability obtained by the WHO and the modified ICDAS method is shown in Table 4.19. The overall intra-examiner reproducibility was higher with the WHO method in contrast to the modified ICDAS index. However, in the case of the modified ICDAS, higher kappa values were recorded at cut-offs related to the cavitated lesion.

Table 4.19: Comparison of intra-examiner reliability values (95% CI) obtained by WHO criteria and by modified ICDAS criteria with cut-off 1, 2 and 3.

	WHO	Modified ICDAS
DMFS	0.84 (0.74-0.94)	0.66 (0.57-0.74)
Modified ICDAS cut – off score 1	n/a	0.48 (0.32-0.65)
Modified ICDAS cut – off score 2	n/a	0.87 (0.76-0.98)
Modified ICDAS cut – off score 3	n/a	0.90 (0.84-0.97)

Cohen’s Kappa statistic, n/a Not applicable

4.7 Predictability of reduced Cariogram and caries increment

The caries prevalence, according to WHO methods were 21% at baseline, 24% at first follow-up, 29.8% at second follow-up, and 38.7 % third follow-up. At baseline, the reduced Cariogram assigned 39.8% children to low, 30.5% of children to medium, and 29.7% to high-risk category. After 18 months, 73% of the high risk, 59% of the medium risk, and 41% of low-risk children show caries increment respectively.

ROC curve was generated to evaluate the predictability of the reduced Cariogram, using adjusted caries increment among cavitated plus non-cavitated lesion (Cut off A-6) after 6, 12 and 18 months and risk levels established at baseline (Figure 4.3). At the first follow-up (6 months) the area under the curve for reduced Cariogram model was 0.63 (95% CI 0.55-0.71; $p<.002$). The sensitivity and specificity were estimated from Youden's analysis using a cut-off value of 31.16. At first follow-up (6 months), the reduced Cariogram demonstrated a sensitivity of 70% and a specificity of 60%.

At the second follow-up (12 months), the area under the curve for reduced Cariogram model was 0.65 (95% CI 0.57-0.73; $p<.0001$). The sensitivity and specificity were estimated from Youden's analysis using a cut-off value of 29.82. After 12 months the reduced Cariogram demonstrated a sensitivity of 66% and a specificity of 64%.

At the third follow-up (18 months), the area under the curve for reduced Cariogram model was 0.70 (95% CI 0.59-0.74; $p<.0001$) indicating that reduced Cariogram model is reasonably useful for predicting caries increment. The sensitivity and specificity were estimated from Youden's analysis using a cut-off value of 29.90. At this cut-off, the reduced Cariogram demonstrated a sensitivity of 70.15% and a specificity of 60%.

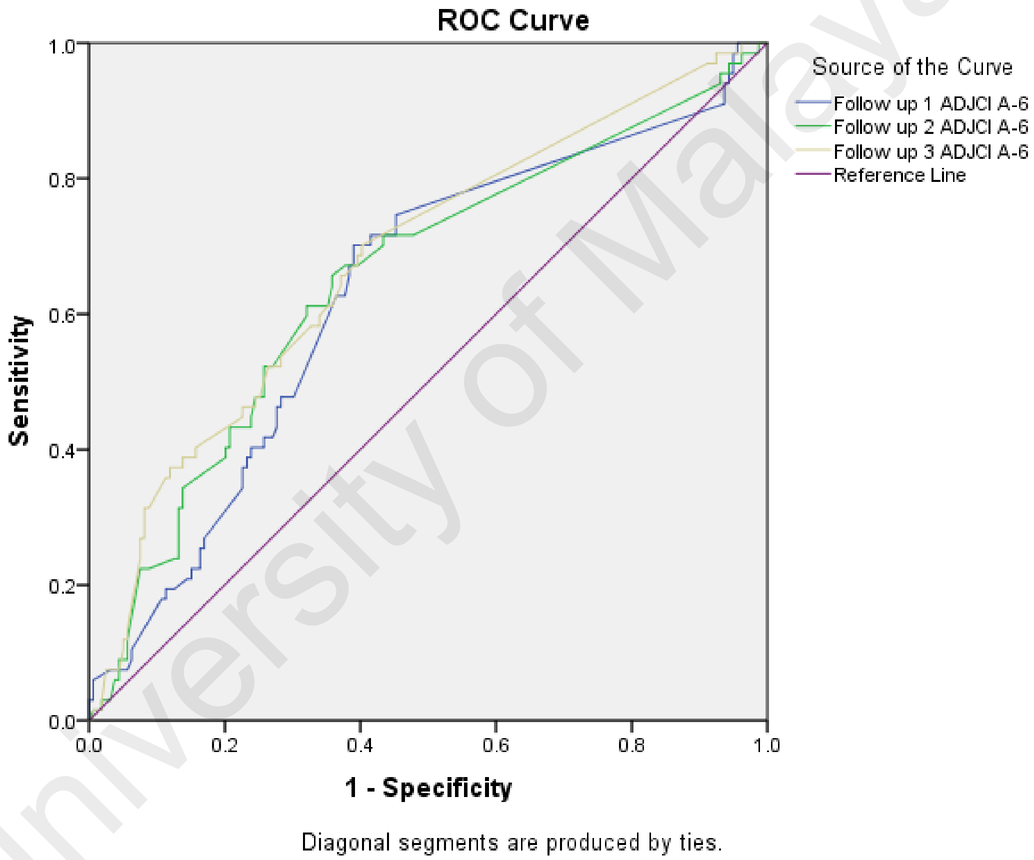


Figure 4.8: : ROC curve at 6, 12 and 18 months.

The adjusted caries increment at all follow-ups according to the chance to avoid caries is shown in Table 4.20. Significant differences in the mean caries increment were observed on all follow-ups at both cut-offs according to the chance to avoid caries. The highest mean caries increment on both cut-offs was observed in children with 0% to 40% chance of avoiding caries at all follow-ups. A gradual decrease in mean caries increment was seen as the chance to avoid caries increases. The result shows that the lowest mean caries increment was observed in children with 81-100% chance to avoid caries at both cut-offs on all follow-ups.

Table 4.20: Adjusted caries increment rate at each follow up according to the chance to avoid caries risk.

	A chance to avoid caries				
	0-40% mean ± SD High risk	41-60% mean ± SD Medium risk	61-80% mean ± SD Low risk	81-100% mean ± SD Very low risk	p-value
Cavitated lesion (3-6)					
Follow-up 1	1.23 ± 1.99	0.37 ± 1.33	0.09 ± 0.73	0.05 ± 0.38	<0.001
Follow-up 2	1.78 ± 3.54	0.46 ± 1.83	0.11 ± 0.53	0.22 ± 0.92	<0.001
Follow-up 3	1.92 ± 3.16	0.69 ± 2.17	0.49 ± 1.69	0.19 ± 0.87	<0.001
Non-Cavitated + Cavitated lesion (A-6)					
Follow-up 1	3.05 ± 3.53	2.41 ± 3.27	1.14 ± 2.06	0.47 ± 1.69	<0.001

Follow-up 2	3.50 ± 3.81	2.41 ± 3.30	1.51 ± 3.57	0.69 ± 3.05	<0.001
Follow-up 3	3.95 ± 4.31	2.51 ± 4.10	1.75 ± 4.11	0.26 ± 1.70	<0.001

One-way ANOVA analysis

Note: This p-value represents the difference of caries increment for categories of a chance to avoid at each time period (Row-wise)

The adjusted caries increment at all follow-ups according to the risk level identified at baseline is shown in Table 4.21. At all follow-ups, when caries risk levels were compared, significant differences in caries increment at both cut-offs were seen. At all follow-ups, caries increment on both cut-offs increased with the caries risk. The highest caries increment was recorded at third follow-up among high-risk children at cut-off 3-6 (1.95±3.18) and A-6 (4.01±4.31). However, the lowest caries increment was recorded at third follow-up among low-risk children at cut-off 3-6 (0.18±1.42) and A-6 (1.11±3.33).

The overall caries increment at cut-off 3-6 was 0.49±1.45 at first follow-up, 0.66±2.35 at second follow–up and 0.86±2.39 at third follow-up respectively. At cut-off A-6, caries increment was 1.99±3.05 at first follow up, 2.24±3.60 at second follow–up and 2.30±4.05 at third follow-up respectively Table 4.21.

Table 4.21: Adjusted caries increment rate at each follow up according to the caries risk level identified at baseline.

	Risk levels			p-value	Overall caries increment
	Low mean ± SD	Medium mean ± SD	High mean ± SD		
Cavitated lesion (3-6)					
Follow-up 1	0.02 ± 0.60	0.40 ± 1.35	1.22 ± 2.01	<0.001	0.49±1.45
Follow-up 2	0.00 ± 0.79	0.45 ± 1.82	1.78 ± 3.57	<0.001	0.66±2.35
Follow-up 3	0.18 ± 1.42	0.70 ± 2.17	1.95 ± 3.18	<0.001	0.86±2.39
Non-Cavitated + Cavitated lesion (A-6)					
Follow-up 1	0.84 ± 1.92	2.49 ± 3.29	3.01 ± 3.54	<0.001	1.99±3.05
Follow-up 2	1.21 ± 3.38	2.41 ± 3.30	3.47 ± 3.82	<0.001	2.24±3.60
Follow-up 3	1.11 ± 3.33	2.48 ± 4.11	4.01 ± 4.31	<0.001	2.30±4.05

One-way ANOVA analysis

Note: This p-value represents the difference of caries increment for risk levels at each time period (Row-wise).

At cut-off 3-6, using repeated measures, ANOVA and Greenhouse-Geisser correction, no significant difference was observed in the mean caries increment between time points within a low-risk category (p=0.31) (Table 4.22). However, a significant difference in the mean caries increment between time points was found at the same cut-off within the medium (p=0.01) and high-risk categories (p=.001). At cut-off A-6 repeated measures, ANOVA using Greenhouse-Geisser correction shows a significant difference in the mean caries increment between time points within the low (p=.001), medium (p=.0001) and high risk (p=.0001) categories respectively.

Table 4.22: Comparison of mean caries increment within risk levels

Baseline	Follow-up 1 (6 months)	Follow-up 2 (12 months)	Follow-up 3 (18 months)	
Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	P value
Cavitated lesion (cut-off 3-6)				
Low 0 ± 0	0.02 ± 0.60	0.00 ± 0.79	0.18 ± 1.42	0.31
Medium 0 ± 0	0.40 ± 1.35	0.45 ± 1.82	0.70 ± 2.17	0.01
High 0 ± 0	1.22 ± 2.01	1.78 ± 3.57	1.95 ± 3.18	.001
Non Cavitated + Cavitated lesion (Cut-off A-6)				
Low 0 ± 0	0.84 ± 1.92	1.21 ± 3.38	1.11 ± 3.33	.001
Medium 0 ± 0	2.49 ± 3.29	2.41 ± 3.30	2.48 ± 4.11	.0001
High 0 ± 0	3.01 ± 3.54	3.47 ± 3.82	4.01 ± 4.31	.0001

Repeated measures ANOVA
Note: This p-value represents the difference of caries increment for within risk levels at each time period (Row-wise).

The comparison of mean caries increments that occurred at all follow-ups within each risk level as compared to baseline is shown in Table 4.23. The post hoc analysis reveals that at cut-off 3-6, in a high-risk category mean caries increment was higher clinically and statistically at all follow-ups as compared to baseline. At cut-off A-6 within all risk categories, a mean caries increment was higher statistically at all follow-ups as compared to baseline.

Table 4.23: Comparing the baseline mean caries increment with the increment occurred at all follow-ups within each risk category.

	Baseline	Follow-up 1 (6 month)		Follow-up 2 (12 month)		Follow-up 3 (18 month)	
	Mean ± SD	Mean ± SD	P value	Mean ± SD	P value	Mean ± SD	P value
Cavitated lesion (3-6)							
Low	0 ± 0	0.02 ± 0.60	1.0	0.00 ± 0.79	1.0	0.18 ± 1.42	1.0
Medium	0 ± 0	0.40 ± 1.35	0.09	0.45 ± 1.82	0.24	0.70 ± 2.17	0.052
High	0 ± 0	1.22 ± 2.01	.0001	1.78 ± 3.57	.001	1.95 ± 3.18	.0001
Non-cavitated plus cavitated lesion (A-6)							
Low	0 ± 0	0.84 ± 1.92	.000	1.21 ± 3.38	.006	1.11 ± 3.33	0.01
Medium	0 ± 0	2.49 ± 3.29	.0001	2.41 ± 3.30	.0001	2.48 ± 4.11	.0001
High	0 ± 0	3.01 ± 3.54	.0001	3.47 ± 3.82	.0001	4.01 ± 4.31	.0001

Repeated Measures ANOVA post hoc Analysis

4.8 Summary of results

For objective 1: To determine the caries risk levels using reduced Cariogram and caries risk predictors in 11-12-year-old Pakistani children.

The present study has shown that the reduced Cariogram can determine children caries risk levels. The most reliable significant predictor associated with caries experience was cariogenic food intake before bedtime and previous caries experience. The reduced Cariogram identified about 39.8% of children as low risk, 30.5% as medium risk and 29.7% as high risk.

For objective 2: To assess the agreement between modified ICDAS and the WHO method on caries detection rate.

Statistically, there was no significant variation in the values of DMFS/DMFT and prevalence of dental caries by the WHO method as compared to the modified ICDAS at cut-off 2 (Code 3-6). The average time spends on the application of modified ICDAS was significantly higher as compared to WHO methods.

For objective 3: To determine the predictability of edurced Cariogram by comparing the caries risk profile established at baseline with the caries increment on follow-up at 6, 12 and 18th month.

At the first follow-up (6 months) the area under the curve for reduced Cariogram model was 0.63 (95% CI 0.55-0.71; p<.002). At the second follow-up (12 months), the area under the curve for reduced Cariogram model was 0.65 (95% CI 0.57-0.73; p<.0001). At the third follow-up (18 months), the area under the curve for reduced Cariogram model was 0.70 (95% CI 0.59-0.74; p<.0001). This indicates that the reduced Cariogram model is reasonably useful for predicting caries increment. The study findings reveal a gradual decrease in mean caries increment with the increase in chance to avoid caries. On the other hand, the results reveal a gradual increase in caries increment as the caries risk of the children increases. In this study, the reduced Cariogram has demonstrated high sensitivity and low specificity.

For objective 4: To determine the rate of caries increment over an 18-month period using WHO method & ICDAS and to recommend an appropriate dental recall interval.

When caries increment was compared within the risk levels at cut-off 3-6 in the high-risk category, mean caries increment was higher statistically at all follow-ups as compared to baseline. At cut-off A-6 within all risk categories, mean caries increment was higher statistically at all follow-ups as compared to baseline.

Based on aforementioned findings, recall intervals for caries management in cavitated lesion is 12 months for low-risk and medium-risk children, and six months for high-risk Pakistani 11-12-year-old children respectively. On the other hand, recall intervals for caries management in both non-cavitated and cavitated lesion is 6 months for low, medium-risk and high-risk Pakistani 11-12-year-old children respectively.

CHAPTER 5: DISCUSSION

Pakistan is a developing country with rapid population growth, and with it comes a burden of multitude of disease with high mortality rates and heavy financial consequences. However, disease management is given low priority with a reduced allocation of resources, as financial ability is very restricted. Oral health surveys conducted in Pakistan shows the evidence that the current oral health care system has not been able to reduce the burden of oral diseases in the country, as there is still a high level of unmet dental treatment needs. There is a need to reorient current oral health services to one that focuses on less expensive technology to treat the population in real need of dental treatment. Therefore, to utilise limited resources effectively, it is necessary to determine the risk levels to prescribe the appropriate recall interval for caries management.

5.1 Caries risk assessment

Caries risk assessment includes the assessment of caries diseases indicators, caries risk factors and protective factors to forecast future dental caries and to report on the factors that contribute most to the caries incidence in the individual (Cabral et al., 2014). Many validated caries risk assessment (CRA) tools have been developed to support oral health professionals in determining the caries risk profiles of their patients. It is suggested that the selected CRA tool must be simple and cheap with limited equipment, and the technique utilised must be acceptable and comfortable for patients (Lee et al., 2013). In this study, the reduced Cariogram tool, without saliva and microbial tests, was employed to assess the caries risk levels of our participants. By excluding the abovementioned tests, the Cariogram ability to predict caries risk may be weakened (Petersson et al., 2010b). However, saliva and microbial analyses have been shown to have low predictive values in relation to dental caries and not practical for routine use in clinical practice (Fontana & Gonzalez, 2012). Also, in the presence of fluoride, caries causing microorganism may be tolerated in the oral cavity without damaging the dentition (Cabral et al., 2014). Hence, based on these factors, the reduced Cariogram ability to predict caries risk in our samples may be slightly compromised. The valuable trade-off, however, is that it can easily and routinely be used in a community setting. Moreover, a recent study has reported that the exclusion of saliva tests from Cariogram does not significantly affect the accuracy of the reduced Cariogram (Dou et al., 2018).

In this study, the majority of low-risk children were from privately funded schools, as compared to the medium and high-risk children who were from the public funded schools. The prevalence of dental caries was also higher in children from public-funded schools (73%) compared to their counterparts (27%). The mean score of the early carious lesions of the samples in this study was 3.1, and this was significantly higher in children from government-financed schools as compared to their counterparts. In addition to that, the mean caries increment after 18 months was also greater in children with higher risk categories where the majority of were from the government-funded schools. A similar finding was reported in other studies conducted using Cariogram (Campus et al., 2012; Garg et al., 2018). This effect may be because in Pakistan, most school children belonged to public schools are from low socio-economic areas, and they lack oral health awareness, poor oral hygiene practices and lack of access to oral health care (Mohiuddin et al., 2015).

The findings of our study show that most 11-12-year-old Pakistani school children were in the low caries risk group with almost absence of caries (DMFT equal 0). The possible explanation for a low mean DMFT scores in a low-risk group may be the low frequency of sugar intake and access to the fluoride toothpaste (Table 4.8). On the other hand, higher mean DMFT score was recorded in higher caries risk children. As indicated in our study the consumption of sugar-containing food was higher in high caries risk children. Although most children in Pakistan have access to water from natural resources which is high in fluoride, evidence has suggested that even in the presence of fluoridation, if the sugar intake is high, dental caries can still occur (Ruottinen et al., 2004; Masson et al., 2010).

In this study, the chance to avoid caries was divided into five categories which are 0-20%, 21-40%, 41-60%, 61-68% and 81-100%, but no participant was identified with less than 20% chance to avoid caries. This may be because we have used the reduced Cariogram without saliva and microbial testing. Previous studies which used the full Cariogram, the chance to avoid caries was classified into five categories which are 0-20% as a very high risk, 21-40% as high risk, 41-60% as medium risk, 60-80% as low risk and 81-100% as very low risk (Peker et al., 2012; Giacaman et al., 2013; Petersson and Twetman, 2015). In those studies, the numbers of participants identified in a very low-risk category were lower as compared to low-risk category. Similarly, the numbers of participants identified in the very high-risk category were lower as compared to the high-risk category. For example, Peker et al., (2012) identified 13.3% participants as very low risk and 42.2% in low-risk categories. Similarly, 3.3% were identified as very high risk and 6.7% as high risk. Another study by Giacaman et al., (2013), identified only 3 participants with very low risk and 39 participants as low risk. Similarly, 31 participants were identified with very high risk and 107 participants with high risk. The appropriate approach is to classify chance to avoid caries in 3 categories (low, medium and high). Similarly, the chance to avoid caries in 3 categories, 0-40%, 41-60%, 61-100% was used in previous studies (Naik et al., 2018; Kavaadia et al., 2012). The use of three categories is most appropriate because the treatment approaches proposed by Cariogram for low risk and very low risk and high risk and very high-risk categories are almost similar.

Caries prevalence and DMFT score was 0 in low-risk children. On the other hand, high-risk children had the highest mean DMFT score (1.51), and their caries prevalence was also high at 71.7%. This indicates that prevalence is directly related with the mean DMFT score. At certain mean DMFT level, the shape of the frequency distribution is similar for all individuals with that DMFT score (Sheiham & Sabbah, 2010).

The mean DMFT scores of 12-year-old Pakistani children in this study were generally very low ranging between 0-1.51. Local cross-sectional surveys conducted on the same age group also provided similar observations where the DMFT scores ranged between 0.90-1.38 (Government of Pakistan, 2003; Mohiuddin et al., 2015; Umer et al., 2016).

In establishing the factor predicting caries risk in our sample population, past caries experience was found to be the most significant variable. Similar findings are reported in previous studies that used the Cariogram tool on 10-11-year-old school children in Sweden (Petersson et al., 2002) and Brazilian 7-9-year-old school children (Campus et al., 2012). Indeed, epidemiological studies have shown a strong positive correlation between past caries experience and future caries development (Fontana & Gonzalez, 2012). The predictive power of this indicator is approximately 60% (Yip & Smales, 2012) and prior caries experience has been declared as the most dominant sole predictor of future carious lesions (Young & Featherstone, 2013). However, the past caries experience is not a causal factor. The progression or regression of caries depends on the exposure of the modifiable risk factors such as sugar content in diet and bacteria in saliva or plaque and the attendance of protective elements such as fluoride and dental sealants (Petersson et al., 2002).

5.2 Dietary assessment

In children, the assessment of dietary free sugars (DFS) intake, especially with regards to its frequency and patterns of consumption is critical not only in preventing the occurrence of dental caries but also other sugar-associated non-communicable diseases. The current study shows that the mean frequency of DFS intake in school-children was approximately five times per day. Studies have shown that caries development among children is low when the consumption is limited to four times a day (Holbrook et al., 1995; Limeback et al., 2012; Viswanath & Sabu, 2014). As observed in this study, children who took DFS less than four times a day had a lower caries experience compared to those who had a higher frequency of DFS intake. Increase in the frequency of DFS intake can cause a reduction in the potential of hydrogen (pH) value of dental plaque for a longer duration and lengthen the active clearance period and consequently leads to higher risk of initial enamel dissolution (Hashizume et al., 2011).

The frequency of DFS intake among children was also higher when they were at home compared to when they were at school. A similar study in the United States reported that more than 60% of added sugars consumed were taken at home as opposed to when away from home (Welsh et al., 2011). One possible explanation for this observation is that in Pakistan, the majority of parents did not encourage children to adhere to a healthy diet (Ahmed et al., 2016). This may be related to the parents' oral health literacy. Currently, in Pakistan, there are no studies that have reported on the level of health or oral health literacy among parents. The importance of assessing parents' oral health literacy cannot be neglected because it has been considered an important determinant of oral health (Naghibi Sistani et al., 2013). In addition to that, evidence shows that caregiver's low level of health literacy is associated with child's high caries risk, night-time bottle-feeding habit, lack of daily brushing, and less dental fillings (Vann et al., 2010; Khodadadi, 2016). This indicates that the assessment of parents' oral health literacy requires utmost attention in any oral health promotion programmes. Appropriate health promotion strategies, which can directly improve parental oral health literacy, can have a beneficial impact on the children's oral health status.

The patterns or the timing of DFS intake can influence the development of caries. The present study shows a significant relationship between children's caries history and consumption of DFS in between main meals, and within two hours before bedtime. DFS should only be consumed at mealtimes when the salivary flow is higher due to stimulation during meals. When salivary flow is high, plaque acids can be neutralised rapidly, and this will consequently lower the risk of caries incidence (Moynihan & Peterson, 2004). The significant relationship between intake of DFS before bedtime and $D_{4-6}MFT$ concurred with previous studies (Levine et al., 2007; Goodwin et al., 2017). Both the current and an earlier study by Goodwin et al., (2017) found that DFS intake before bedtime explained about 70% of caries experience. Goodwin et al. (2017) also reported that the DMFT increment for subjects who consumed one DFS snack before bedtime was over twice those who did not. The salivary flow rate and its buffering capacity are low during bedtime. These factors could cause a sustained low plaque pH level, which then may lead to caries.

5.3 Correlation between WHO and modified ICDAS

The conventional WHO method used for caries diagnosis in Pakistan has numerous limitations (Pitts, 2008). One of the significant restrictions is that it only records visible carious lesions and does not provide additional information regarding the state and stages of caries. However, the Cariogram supports the use of WHO methods for caries risk estimation.

To overcome the limitations of the WHO method, modified ICDAS was developed where early and accurate information regarding the type, location and depth of carious lesions is recorded, which helps practitioners in the selection of appropriate precautionary and curative approach. Most carious lesions are now found at earlier stages, and the use of an index, which can record both cavitated and non-cavitated lesions, will improve the sensitivity of caries detection (Henry et al., 2017). The Cariogram does not support the use of ICDAS. However, the application of two caries measurement system at the time of caries risk assessment can cause bias and make this exercise time-consuming. The findings of our study reveal that at Code 3, the modified ICDAS is comparable with the WHO criteria. This shows that DMFT scores can be extracted from the modified ICDAS by converting cavitated lesions recorded with ICDAS Codes 3-6 to its respective WHO score. The converted DMFT/DMFS scores obtained can be entered in the reduced Cariogram for risk assessment. The missing and filled components can be estimated by using the first code of the ICDAS score. The adoption of modified ICDAS will prevent the application of two separate caries measurement systems at the time of risk assessment.

The findings of our study also revealed that despite having a significant advantage over the DMFT criteria, the common problem encountered with using modified ICDAS is the longer time required for oral examination. In this study, the estimated mean time difference between using the modified ICDAS and WHO methods was almost two minutes which is not significant and can be overcome by the examiner's calibrations and training.

The outcome of our study showed the equivalences between the WHO and modified ICDAS indices for all the three parameters assessed (DMFS, DMFT and overall caries prevalence) at cut-off point 2, where modified ICDAS Codes 0 and A were considered as sound and Codes 3-6 were classified as carious. This finding can be considered similar to a previous study conducted on 12-year-old children in Spain, although different cut-off points were used (IranzoCorte's & AlmerichSilla, 2013). IranzoCorte's & AlmerichSilla (2013) also reported that when full ICDAS Codes 0-1 were considered as sound, no significant difference was found in the mean DMFT scores. In the case of mean DMFS score, no significant difference was found where full ICDAS Codes 0-2 were classed as healthy.

The application of full ICDAS requires compressed air to detect Code 1, 2 and 3 (De Amorim et al., 2012). However, Code 1 and 2 are enamel lesions with little difference in the mineral loss, and they require the same preventive treatment. This makes reporting of Code 1 and 2 separately in an epidemiological survey questionable. In our study, we used a modified ICDAS index in which Codes 1 and 2 are merged and recorded as 'A'. Evidence shows that in field studies, drying can be done with cotton wool/gauzes. However, it requires the merging of Code 1 with Code 2 (Pitts, 2009; Tomita et al., 2014). On the other hand, the ball ended WHO probe can be used to identify Code 3 lesions. Therefore, in the case of an epidemiological survey, the simple approach is not to assess Code 1 and 2 separately (De Amorim et al., 2012).

Similarly, previous studies have used the full ICDAS done on preschool children have also demonstrated that the cut-off point where modified ICDAS Codes 3-6 were considered as carious exhibits discriminant validity similar to the WHO criteria (Braga et al., 2009a: Mendes et al., 2010). The histological evidence provides a possible explanation for this that at Code 3; the carious lesion has advanced beyond enamel (Braga et al., 2009b). Therefore, at this stage, caries may have penetrated in dentin, and due to this it can be measured and compared according to the WHO criteria (Braga et al., 2009a; IranzoCorte's & AlmerichSilla, 2013).

When the non-cavitated lesions were combined with cavitated lesions, almost three times increase in the mean DMFT/DMFS scores and the prevalence of dental caries was observed (Table 4.18). Previous evidence shows that the exclusion of the non-cavitated lesions consequently results in the loss of half of caries experience (David, 2006). When non-cavitated lesions are not measured, most of these lesions will not get treated and may later develop into cavitated lesions, which then require invasive therapy. Therefore, the rational approach is to use an index that can measure early carious lesion.

The two methods that are currently in use to detect non-cavitated lesions are the ICDAS II and Nyvad criteria. For the high-risk population, the appropriate system is ICDAS II because it has a higher sensitivity level for detecting early carious lesion (Braga et al., 2009; Mitropoulos et al., 2010). However, the use of a caries detection method with higher sensitivity for initial carious lesion may result in a high prevention cost. Nevertheless, it allows practitioners to use appropriate preventive strategy, and this will prevent the disease to occur or to progress at little cost for preventive treatment (Zero et al., 2001; Kraglund, 2009).

5.4 Predictability of reduced Cariogram

In this study, the predictability of reduced Cariogram was evaluated to determine whether it can predict caries increment among caries risk levels identified at baseline in a statistically significant way at 6, 12 and 18 months. Based on this, recommendations can be made for appropriate caries recall interval. In this study, the caries risk levels identified at baseline, and adjusted caries increment occurred at 6, 12, and 18 months were used to measure the predictability of reduced Cariogram.

The accuracy of reduced Cariogram was 0.63 after six months and 0.65 after 12 months and 0.70 after 18 months. Peterson et al. (2010b) and Gao et al. (2013) have reported a similar accuracy of reduced Cariogram after 12-24 months. There is no literature available regarding the predictability of reduced Cariogram after six months. The time reported in studies to verify Cariogram predictability in a statistically significant way is 12-24 months (Peterson et al., 2010b; Campus et al., 2012; Gao et al., 2013; Sudhir et al., 2017; Dou et al., 2018). However, the outcome of this study shows that the reduced Cariogram can also predict caries increment as early as six months. The low accuracy of reduced Cariogram at early follow-ups may be due to the low overall caries increment at cut-off A-6 on earlier follow-ups as compared to the follow-up at 18 months (Table 4.21).

The sensitivity and specificity of reduced Cariogram obtained in this study was 70% and 61% respectively at 6-month, 66% and 64% respectively at 12-months and 70.15% and 60% at 18-months respectively. Peterson et al. (2010b) also reported high sensitivity and low specificity of the reduced Cariogram in a two-year prospective study on school children. However, Gao et al., (2013) have reported a low sensitivity and high specificity of the reduced Cariogram in a 12-month follow-up study on pre-school children. The difference in the levels of sensitivity and specificity observed may be due to the differences in the methods used to select the cut-off point for the estimation. To estimate the sensitivity and specificity of the reduced Cariogram, 38.5% chance to avoid caries was used by Gao et al., (2013). The use of single defined criteria to determine sensitivity and specificity can incorporate bias. However, in this study, the highest value of Youden's analysis was used as a cut-off point to estimate sensitivity and specificity which maximises the correct classification rate by assigning equal weights to the sensitivity and specificity (Yin & Vogel, 2017). The possible explanation of the low sensitivity observed after 12 months in this study is may be due to the low occurrence of caries, or the regression of carious lesion which occurred at cut-off A-6 in medium risk participants.

The increased caries sensitivity of a risk assessment tool may increase the number of false-positive results and expose patients to overtreatment. However, findings from previous studies by Peterson et al. (2010a) and Sudhir et al. (2017) indicate that clinically it is essential to identify individuals at high caries risk compared to individuals with low caries risk. The application of the test with higher sensitivity can result in a high prevention cost. However, if practitioners use appropriate preventive strategy, this would cause very little harm to the patient by not permitting the disease to occur or progress at little cost for preventive treatment (Zero et al., 2001; Kraglund, 2009).

In this study, the mean caries increment increased across the caries risk groups at all follow-ups as compared to baseline. A similar trend was reported in studies conducted by Peterson et al. (2010a) and Sudhir et al. (2017). Furthermore, our results show that the mean caries increment was higher in high-risk children as compared to the low-risk children at all follow-ups. Similarly, a ten-fold increase in the mean caries increment was reported among high-risk children as compared to the low-risk children by Bratthall & Hansel (2005) and Garg et al. (2018). A possible explanation for this trend in high-risk children can be the high consumption of cariogenic food and the high frequency of sugar intake (David, 2006).

5.5 Caries increment rates

Longitudinal studies conducted on captive population such as school children or soldiers can provide useful estimates of dental caries increment over a period of time. However, to our knowledge, longitudinal studies assessing caries increment have never been conducted on Pakistani population; thus, comparison at the national level is not possible. Also, studies conducted on non-Pakistani school-age population reports caries increment only among cavitated lesions. Ismail et al.'s study conducted in 2011 is the only one so far that estimated caries increment on both cavitated and non-cavitated lesion. However, the comparison of the current findings with that study is not possible because their assessments were carried out only on primary dentition, by using different follow-up period, and caries risk levels of participants were not determined.

Abanto et al. (2015) conducted a study to assess the effectiveness of a preventive programme on the incidence and regression of initial carious lesions in 1-12-year-old children by categorising them according to caries risk category. This study was of 12 months duration, and follow-up assessments were carried out at 4, 8 and 12 months during which preventive measures were applied. However, a direct comparison of the current findings with that study is not possible because of the different follow-up period used, the distribution of participants according to their caries risk level is not explicitly reported, and the caries increment that occurred in non-cavitated lesion was not reported according to the follow-ups. The only finding which was similar to our study is that higher incidence of the carious lesion was reported in participants who had higher mean DMFT score at baseline.

Gao et al., (2015) conducted a prospective study of 18-month duration on 3-year-old children by categorising them according to risk categories using Cariogram. The caries increment was measured only among cavitated lesions. After 12 months the mean caries increment was 0.34 in the very low-risk category, 0.72 in a low-risk category, 1.02 in a medium risk category and 2.07 in a high-risk category. The mean caries increments as found in our study are lower than that as reported by Gao et al., (2015) (Table 4.20). This may be because the former study had only assessed caries increment in deciduous dentition where caries progression is rapid due to reduced enamel thickness. Further comparison with this study is not possible because increment occurred at 6 and 18-month follow-up is not reported.

Sudhir et al. (2017) conducted a prospective study of 18-month duration in India on 12-year-old institutionalised children by categorising them according to their caries risk levels using Cariogram. Sudhir only measured caries increment among cavitated lesions only after 18 months. They reported that the overall mean caries increment after 18 months was 0.55±0.80 and 100% of the high risk, 57% of the medium risk, and 18.18% of low-risk children show caries increment respectively. In addition to that, after 18-months, the mean caries increment of their samples was 0 in the very low-risk category, 0.27 in the low-risk category, 0.71 in the medium risk category and 0.85 in the high-risk category. In our study after 18 months at cut-off 3-6, the overall mean caries increment was 0.86±2.39 and 73% of the high risk, 59% of the medium risk, and 41% of low-risk children displayed caries increment (Table 4.20). The low mean caries increment reported in their study may be related to the motivation of children towards preventive measures provided to them and the recommendations of home care.

The DMFT score of low-risk participants in this study was zero at baseline. After 18 months, the mean caries increment was 0.18 at cut-off 3-6, and 1.11 at cut-off A-6 which were lower as compared to the mean caries increment occurred in higher risk categories in this study on the same cut-off. These findings are in accordance with the findings of Sheiham & Sabbah (2010) who reported that caries progression is slower in a population with low mean DMFT scores.

The caries increment within each risk category was measured on all follow-ups at cut-off 3-6 and A-6 (Table 4.23). At both cut-offs, high mean caries increment was observed in high-risk children on all follow-ups as compared to low and medium risk children. Evidence has suggested that caries increment rate is higher in the high-risk children as compared to low and medium risk (National Collaborating Centre for Acute Care, 2004). This effect may be due to the high consumption of sugar-containing diet by high-risk children. At cut-off A-6, low mean caries increment was observed in low-risk children at 18 months. Similarly, in medium risk children at cut-off A-6, less mean caries increment was observed at 12 months. The possible explanation of reduced caries increment on these follow-ups is the regression of early carious lesion.

5.6 Recommendation for caries recall interval according to caries risk levels

The debate on the appropriate timing of recall interval for a dental check-up was fuelled by the growing realisation regarding the increasing demand of oral health care, management of oral health resources and the lack of evidence regarding proper timing of recall visits. Another factor that contributes to this debate is the lack of sufficient scientific evidence to support the use of 6-month recall interval (Riley et al., 2013; Pitts, 2009). Moreover, the recent paradigm shift in caries management approach from repair and restoration to prevention and conservation also contribute to this debate (Pitts, 2009).

Caries risk assessment is an essential part of patient centred caries management (Tellez et al., 2013). Caries risk assessment is conducted to evaluate the patient’s risk level, plan recall interval, determine and select diagnostic and treatment procedures, identify major causative elements and to investigate the number of new incipient or cavitated lesion. Caries risk assessment is a complicated procedure that involves the consideration of several risk factors to predict caries risk level. For example, diet, microflora, susceptible host, a mixture of social, behavioural and cultural agents, previous caries experience, and the presence of early enamel lesion, are all risk factors for dental caries (Zero et al., 2001; Hallet, 2013; Zukanović, 2013; American Academy of Paediatric Dentistry, 2014). As mentioned previously, the most powerful risk predictor of future caries risk is previous caries experience. However, it should only be considered as a risk marker because it is not a causal factor. Other modifiable risk factors such as bacteria, diet and fluoride are more important to define caries risk levels (Petersson et al., 2002).

There are three levels of caries risk namely low, medium and high. The categorisation of individual according to caries risk is necessary because each risk category has different recall intervals and treatment approaches. The purpose of caries recall interval is to reassess and monitor patient's compliance with advice, to promote positive patient behaviour, and to maintain their oral health by limiting the progression of oral disease at the earliest stage as possible after onset (Pitts et al., 2014). It is suggested that the timing and frequency of recall interval should be adjusted according to the risk level (Pitts et al., 2014) because the occurrence and progression of disease depend on the patient's risk. Shorter recall intervals are suggested for individuals with higher risk level and vice versa for those in the medium and low caries risk levels.

Depending on caries risk, the recommended range for recall interval between dental examinations varies from 3-12 months for children 18 years and below (National Collaborating Centre for Acute Care, 2004; Pitts et al., 2014; American Academy of Paediatric Dentistry, 2014). Recall interval period up to 12 months provides clinicians with an opportunity to reinforce preventive advice and to raise individual awareness regarding good oral health.

In this study, the recommendation of recall intervals for each risk level was made by comparing the baseline mean caries increment with the mean caries increment that occurred at all follow-ups within risk categories at cut-off 3-6 (only cavitated lesions were considered) and cut-off A-6 (both cavitated and non-cavitated lesions were considered). Both cut-offs were used because the rate of caries progression from enamel to dentine is of fundamental importance to plan recall interval (Sheiham & Sabah, 2010).

At cut-off 3-6 within low and medium risk categories, no significant difference was found in mean caries increment which indicates no caries progression in cavitated lesion up to 18 months (Table 4.23). On the basis of this, for the management of cavitated carious lesion in low and medium risk children, the recall interval can be extended up to at least 18 months. However, it could be contested that children of aged 11-12-year- old are at the stage of personal development; hence it is not advisable to extend the recall interval because all the essential foundations for the lifelong dental health are laid down at this stage. Moreover, recall interval period of more than 12 months can consequently result in loss of professional relationships between clinician and patient (National Collaboration Centre for Acute Care, 2004). A 12-month recall interval period for low and medium caries risk children has also been recommended by the Public Oral Health System in Sao Paulo (Abanto et al., 2015) and the Scottish Dental Clinical Effectiveness Programme (2011). Although there are some advantages of recommending shorter dental recall interval (less than 18 months) for children categorised in low and medium caries risk, the lack of health resources in Pakistan does not permit such shorter recalls to be assigned on its population. In addition, shortening the dental recall interval of those especially in the low caries categories may not provide any major advantage to them in respect of their total disease experience (Sheiham, 1985). Instead, they may face some financial implications including time foregone in attending for appointments, and the enhanced possibility for iatrogenic interventions associated with regular attendance (Sheiham 1985)

Based on the same cut-off, in high-risk children, the difference in mean caries increment was statistically significant from the six months follow-up onwards indicating early caries progression in this category of children (Table 4.23). Hence for the management of cavitated carious lesion in high-risk children, the recall interval cannot be extended beyond six months.

At cut-off A-6 where both non-cavitated lesion and cavitated lesions are considered, the difference in mean caries increment was statistically significant in all risk categories at all follow-ups (Table 4.23). Based on this, the recall interval for caries management of both non-cavitated and cavitated lesions in low, medium and high-risk children cannot be extended beyond six months. The six months recall interval for low, medium and high-risk children is also recommended by the American Academy of Paediatric Dentistry (2014).

In this study, the recommendation for the first recall was made at six months from baseline. However, for children in the higher risk categories, there is a possibility that caries may have occurred even earlier than six months from baseline. If that is the case, caries recall interval should be made earlier than at six months from baseline. For example, a 3-month recall interval is recommended by the American Academy of Paediatric Dentistry (2014) and by the Scottish Dental Clinical Effectiveness Programme (2011). On the other hand, recall interval of 4-8-month between dental examinations is recommended by the Public Oral Health System in Sao Paulo (Abanto et al., 2015). Future studies of this nature in Pakistan should have the first recall interval as early as three months from baseline to accommodate for the high caries increments which occur early in those children at higher caries risk.

Dental recall interval recommended in developed countries may not be applicable in developing countries. For example, the American Academy of Paediatric Association, (2014) recommend recall interval period of 6-12 months for children with low and medium risk and six months for high-risk children. On the other hand, the Public Oral Health System in Sao Paulo recommends only 12 months of recall interval for medium and low-risk children and 4-8 months of recall interval for high-risk children (Abanto et al., 2015). These variations in recall interval may be due to the difference in caries experience, availability of resources and uneven distribution of the oral health workforce. In a situation where resources are scarce, and available oral health workforce is limited, extended recall interval can be used. The use of shorter recall interval in such conditions can result in the waste of resources and reduces the capacity of the health care system.

These frequencies of caries recall examinations are not fixed and can be adjusted, modified or reused not only for the management of caries but also for the periodontal and mucosal health depending on the respective findings of review and monitoring (Pitts et al., 2014). The recall intervals can also be modified depending on the availability of resources and the oral health workforce.

5.7 Application of risk-based recalls in Pakistan

In Pakistan, there is a limited budget allocation for oral health care services as a large part of the overall health budget is devoted to the control of communicable diseases which result in high mortality (Government of Pakistan, 2003). In the case of community oral health services, there are no school-based dental programs offered by the Ministry of Health. School oral health promotion activities are usually arranged by the private and government dental institutes, mostly in urban areas, but not on a regular basis (Haleem, 2006). In Pakistan, the majority of dental practitioners are in the public health sector who mostly reside in urban areas (Haleem & Khan, 2006). Caries prevalence in Pakistan is 50% among its 12-year-old children (Government of Pakistan, 2003). The majority of water supplies in Pakistan have fluoride levels even less than 0.35 ppm (Khan et al., 2004a; Khan et al., 2002). Based on these limitations, the rational approach to adopt in improving the oral health and especially the caries status of its 11-12 years-old children is to provide oral health care services at appropriate intervals on the basis of individual caries risk level.

The adoption of a risk-based approach can be useful in Pakistan because it can reduce the burden on the health care system by identifying an individual in genuine need of dental treatment. Evidence suggests that risk-based recalls are beneficial when resources are scarce. Moreover, risk-based recalls can enhance the function of the health care system to administer care for individuals at significant risk of oral disease (Institute of Medicine and National Research Council, 2011; Riley et al., 2013).

However, the assessment of caries risk level requires a risk assessment tool which is acceptable to both dentist and patient, has acceptable accuracy until the next review, is valid, reliable, predictable and evidence-based yet involve low cost, produce simple outcomes and time-saving, (Peterson et al., 2010a; Brocklehurst et al., 2011). The reduced Cariogram can be applied in Pakistan because its application requires limited resources, the outcome is understandable, the application is easy for a practitioner and requires less time, and it does not include saliva and microbial testing. However, the use of the reduced Cariogram program requires the availability of computers in dental practice. Data indicate that in Pakistan, the majority of the dentist has access to computers in the dental clinics with internet access, and computerisation of government hospitals is ongoing (Qazi et al., 2012).

The risk estimation with reduced Cariogram requires analysis of dietary habits. The 24-hour dietary recall and the 3-day diet diary can be used to assess dietary intake (Bratthall et al., 2004). Three-day diet diary provides reliable information on general food consumption without causing respondents fatigue (Ortega et al., 2015). However, the application of three-day diet diary may not be practical in the community settings. On the other hand, 24-hour dietary recall can be carried out to save time. However, this method does not provide detail dietary analysis but can be performed to analyse a typical dietary pattern in an ordinary day's intake (Bratthall et al., 2004). In Cariogram, other information required is plaque measurements, clinical judgement, and access to fluoride sources. Data regarding these risk factors can be easily collected by conducting clinical examination and by questionnaire.

In Pakistan, the WHO DMFT index has traditionally been used to assess the level of caries at the cavitated level in the population. However, the use of the ICDAS has an advantage as it denotes caries at the level of both the cavitated and non cavitated lesions. Nevertheless, its use in Pakistan requires training of existing dentists most of whom may not be familiar with it. Additionally, there is evidence to show that mean examination time taken when the full ICDAS is applied was twice as long as compared to the use of the WHO index (Braga et al., 2009a). Longer examination time would indirectly increase overall cost in terms of resources required and hence may be a limiting factor in using the index in the public oral care system in Pakistan. However, in this study the estimated mean time difference between using the modified ICDAS and WHO methods was almost two minutes and that the difference was not statistically significant. As the examiners become more familiar and more efficient with the use of the modified ICDAS, the overall time taken can be further reduced.

In the case of Pakistan, the need for school dental care programme is evident. The government of Pakistan should initiate school oral health programs in areas where a majority of the oral health workforce is available by incorporating a risk-based approach to improve oral health. On the other hand, in areas with limited oral health practitioners, dental hygienist, chair side dental assistants and school teachers can also be included in school dental programs after training and workshops (Haleem & Khan, 2006). Adding risk-based recalls in school dental programs will direct limited resources towards the children in urgent need of care.

5.8 Discussion related to null hypothesis

If the WHO method is, or continued to be used, on Pakistani schoolchildren for caries measurements, our null hypothesis which stated that caries recall interval for 11-12-year-old Pakistan children, regardless of their caries risk status, is six months, can be rejected. This indicates that the current practice of fixed or 6 months recall visits or problem-oriented visits in Pakistan is not appropriate.

On the other hand, if the ICDAS is adopted in Pakistan for caries detection in the future, the recall interval of 6 months regardless of caries risk can be adopted for caries management among 11-12-year-old Pakistani children. However, the adoption of ICDAS with 6-month recall interval in the future cannot rule out the use of risk assessment tools because diagnostic and treatment approaches are different for each risk category.

5.9 Limitations of the study

In this study, some variables that can play a role in caries development were not included namely saliva and microbial testings. The use of saliva and microbial testing in Cariogram for risk prediction can be more useful among an older population with compromised saliva secretion rate (Campus et al., 2012), but may not be relevant for children because salivary flow abnormalities are rare in children (Gao et al., 2010). Secondly, these tests are costly, time-consuming and not readily available to dental practitioners in clinics and field surveys (Graham, 2009). Moreover, some studies have shown that reduced Cariogram can still be used without performing saliva and microbial testing (Petersson et al., 2010b; Gao et al., 2013).

The assessment of caries was conducted using only visual examination. No radiographic evaluation was used to assess interproximal carious lesions or to confirm the status of unerupted teeth. Hence, caries prevalence and subsequently the calculated caries increment rate may not be truly reflected. Moreover, caries increment rate may be underestimated because ADJCI cannot differentiate between biologically plausible and biologically implausible reversals.

During the study period, no treatment was provided to the study participants by the investigator; however, children in need of urgent dental treatment were advised to visit the dentist in the local district headquarter hospital. Hence, there is a possibility that some participants received preventive care especially children with low caries risk and children from private schools and explains why caries increment is lower in these children. In this case, results may be affected due to the underestimation of caries increment.

Some part of this study heavily relied on the data obtained from the diet diaries that are open to recall bias and under-reporting of food intake. As children were requested to fill in the diaries after the intra-oral examination, this could lead to an increase in their oral health awareness after the clinical examination. However, short interviews were conducted with the participants at the time of submission to verify the data reported to overcome some of these limitations.

Only one examiner was involved in the assessment of caries using both indices. Hence, there is a chance of an examiner bias; however, this was minimised by applying an appropriate washout period in between the two assessments. Nevertheless, inter-examiner variations or bias can also occur if more than one examiner was involved for each system.

Despite several actions taken to ensure the participant's presence on the examination day which includes obtaining the contact information of subjects and reminding them through messages or the telephone call, the participant dropout was high. For health researchers, it is suggested that if a proportion of missing data is more than 5%, the appropriate approach is to employ multiple imputations (Dong & Peng, 2013). In this study, the proportion of missing data was 36.2%. Therefore, to overcome this limitation, multiple imputations were used to substitute the missing data values with the plausible data for statistical analysis. The results from multiple imputations are generally unbiased when the mechanism of missing data is missing at random (MAR) and missing completely at random (MCAR) (Buhi et al., 2008).

This study was conducted in a specific geographical area, and convenience sampling was used, hence the findings may not be generalised to the whole population. However, the findings can be applied to the population with similar characteristics.

5.10 Strengths of the study

As this was the first longitudinal study conducted in Pakistan to measure dental caries increment, it provides unique and valuable information regarding the caries progression rates of children in Pakistan. Moreover, this is the first study that provides data regarding the dental caries status of 11-12-year-old school going children of Bhakkar.

This study categorizes children according to their caries risk levels (low, medium and high). In this part of the world, previous studies on caries progression were carried out without categorising the caries risk level of the population (Wahid et al., 2014; Masood et al., 2014). The assessment of caries risk level is necessary because caries increment rate, recall interval and treatment approaches are different for each risk category.

In this study, we have used an algorithm-based risk assessment tool (Cariogram) in which risk was estimated quantitatively by using a complicated formula containing many 'if' conditions and provide refined risk calculations as compared to reasoning-based tools used in other studies. All factors in Cariogram have been given a specific weight according to the chosen score, and as the scores increase the weight of that factor will be higher (Petersson et al., 2002). In addition, the reduced Cariogram has better sensitivity and specificity when compared to paper-based risk assessment tools where caries risk was estimated qualitatively by considering the preponderance of factor in any risk category and provides only rough risk estimates (Gao et al., 2013; Mitha et al., 2016).

Caries estimation was performed at child level, thus genuinely reflect the initiation of disease in subjects. In addition to that, caries increment rate was measured in cavitated lesion alone and also by combining non-cavitated and cavitated lesions. In the majority of previous studies, caries increment is reported only for cavitated lesions (Vallejos-

Sanchez et al., 2006; Peterson et al., 2010; Campus et al., 2012; Gao et al., 2013; Wahid et al., 2014; Masood et al., 2014). However, the inclusion of non cavitated lesion as employed in this study is to achieve accurate caries progression rates (David, 2006).

In this study, the estimation of sensitivity and specificity was carried out by using receivers operating characteristic (ROC) curve using continues data instead of using a conventional approach of 2 x 2 tables with binary data. Conventional method relies on single defined criteria to determine true positive or true negative results. Bias can occur if the inappropriate cut-off is selected. Another limitation of this method is that the predictive values of the test are sensitive and linked with the disease prevalence in the population. When the prevalence of a disease is higher in population, there is a chance that the positive predictive values will be higher and vice versa. Consequently, it becomes difficult to identify the population with disease (Linden, 2006).

ROC analysis on the other hand estimates model accuracy at the different range of scores and possible decision values are calculated and entered into the analysis. Also, it provides a visual analysis of scores by developing a curve that assists in determining the appropriate trade-off between sensitivity and specificity and accuracy of the test based on the area under the curve (AUC). Moreover, the results provided by the ROC are not affected by the disease prevalence in the samples as it is with the conventional technique (Lasko et al., 2005; Linden, 2006). Petersson et al. (2010b) and Gao et al. (2013) also used ROC analysis to estimate the area under a curve and the sensitivity and specificity of Cariogram.

A 3-day diet diary was used in this study, and it has been considered as a gold standard of dietary assessment methods. Three-day diet diary provides reliable information on general food consumption without causing respondents fatigue (Ortega et al., 2015). Moreover, this is the only study that provides an in-depth analysis of the frequency of sugar intake among Pakistani 11-12-year school going children.

CHAPTER 6: CONCLUSIONS

6.1 Conclusion

This study aimed to recommend the appropriate recall interval for caries management among 11-12-year-old Pakistani children.

The conclusions to be drawn from this study are:

1. The reduce Cariogram is comprehensive but straightforward as it includes elements of the principal aetiological factors of dental caries such as diet content, diet frequency, access to fluoride and oral hygiene and it is useful in determining the caries risk levels.

2. The predictors for future dental caries among Pakistan 11-12-year-old children are previous dental caries experience and cariogenic food intake before bedtime.

3. Modified International Caries Detection and Assessment Systems method can be used in epidemiological surveys as it was found to provide results similar to the World Health Organisation criteria at cut-off point 2.

4. The reduced Cariogram can predict caries increment at 6 months with 63% accuracy, at 12 months with 65% accuracy and at 18 months with 70% accuracy.

5. The caries progression rates are rapid in individuals with higher caries risk and slower in the individual with low caries risk.

6. Risk-based recall intervals for caries management in cavitated lesion are 12 months for low-risk and medium-risk children, and six months for high-risk Pakistani 11-12-year-old children respectively.

7. Risk-based recall intervals for caries management in both non-cavitated and cavitated lesion is 6 months for low-risk, medium-risk and high-risk Pakistani 11-12-year-old children respectively.

6.2 Recommendations

Taking into account the study objectives, limitations, and based on the study findings, below are the overall recommendations that may be useful to improve the oral health status of 11-12-year Pakistani children.

The risk assessment based on quantitative measures must be included in clinical practice to prescribe appropriate recall interval period for the caries management to reduce the unnecessary financial burden on the health care system, and to provide care to the patients in real need of treatment.

In Pakistan, there is a need to incorporate ICDAS in the dental curriculum. The modified ICDAS must be applied in Pakistan in epidemiological surveys so that appropriate treatment and oral health promotion strategies can be planned. Proper training and calibrations of examiners on the ICDAS index must be carried out at national level.

Health promotion efforts at home, schools and community levels need to be intensified to reduce dietary free sugar intake amongst Pakistani school-children.

6.3 Further research

Future studies recommended to be conducted:

1. Similar research to be conducted on a broader scale of Pakistani population but with an earlier follow up period at 2 or 3 months.

2. To estimate the predictability of reduced Cariogram after two years.

3. To estimate the difference in caries progression and recall interval if caries preventive measures are applied at baseline.

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List of Publications

1) Taqi, M, Razak, I.A., Ab-Murat N. (2018) Comparing dental caries status using Modified International Caries Detection and Assessment System (ICDAS) and World Health Organization (WHO) indices among school children of Bhakkar Pakistan. *Journal of the Pakistan Medical Association*, 69(7):950-954.
2) Taqi, M., Razak, I.A., Ab-Murat, N. (2018). Sugar consumption and caries occurrence among Pakistani school children. *Journal of the Pakistan Medical Association*, 68 (10): 1483-1487.
3) Taqi M, Razak IA, Ab-Murat N. (2017). Caries risk assessment in school children using reduced Cariogram model. *Pakistan Journal of Medical Sciences*, *33*(4): 948-952.doi: https://doi.org/10.12669/pjms.334.13106